

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA ex rel.)	CASE NO.: 1:21CV1239
White, et al.,)	
)	JUDGE CHARLES E. FLEMING
Plaintiffs,)	
)	
v.)	
)	
RITE AID CORPORATION, et al.,)	<u>COMPLAINT IN INTERVENTION</u>
)	<u>AND JURY TRIAL DEMAND</u>
Defendants.)	

Plaintiff, the United States of America, by its undersigned counsel, alleges as follows:

1. The present opioid epidemic is a national public health emergency.
2. Hundreds of thousands of Americans have died from drug overdoses over the last decade. According to the Centers for Disease Control and Prevention (CDC), over 90,000 Americans died from drug overdoses in 2020, a 31% increase from 2019. Holly Hedegaard et al., Nat'l Ctr. for Health Stat., NCHS Data Brief No. 428, Drug Overdose Deaths in the United States, 1999-2020, (2021), <https://www.cdc.gov/nchs/data/databriefs/db428.pdf>. Provisional data from the CDC indicates an estimated 107,622 Americans died from drug overdoses in 2021, an increase of nearly 15% from 2020. Press Release, Nat'l Ctr. for Health Stat., U.S. Overdose

Deaths in 2021 Increased Half as Much in 2020 – But Are Still Up 15%, CDC (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

3. Pharmacies serve as critical gatekeepers against the unlawful dispensing of controlled substances. Because pharmacies are the last step in the supply chain before controlled substances are in the hands of individuals, the law vests pharmacies and pharmacists with important obligations to ensure that they fill only legitimate prescriptions. As alleged in this Complaint, Rite Aid filled prescriptions for powerful opioid painkillers, such as oxycodone, fentanyl, and other highly diverted controlled substances that were unlawful and medically unnecessary. By doing so, Rite Aid violated its legal obligations and significantly contributed to this country's opioid crisis.

4. From at least May 1, 2014, through June 10, 2019, Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and their associated state subsidiaries, Rite Aid of Connecticut, Inc.; Rite Aid of Delaware, Inc.; Rite Aid of Maryland, Inc.; Rite Aid of Michigan, Inc.; Rite Aid of New Hampshire, Inc.; Rite Aid of New Jersey, Inc.; Rite Aid of Ohio, Inc.; Rite Aid of Pennsylvania, Inc.; and Rite Aid of Virginia, Inc., (collectively “Rite Aid”) filled at least hundreds of thousands of unlawful prescriptions for controlled substances that were medically unnecessary, lacked a medically accepted indication, or were not issued in the usual course of professional practice.

5. These unlawful prescriptions for controlled substances included prescriptions for “trinities,” a widely known dangerous combination of an opioid, benzodiazepine, and muscle relaxant, desirable by drug abusers because of the increased euphoric effect of taking them together (¶¶ 98-103); “early fills” of fentanyl and oxycodone prescriptions before a prior prescription for the same drug had run out, which is a clear sign of overutilization (¶¶ 117-20);

prescriptions for extremely high doses and excessive quantities of opioids that fed opioid dependence and addiction (§§ 104-16); and prescriptions written by prescribers who Rite Aid’s own pharmacists had repeatedly identified as writing illegitimate prescriptions with no medically valid purpose (§§ 123-26).

6. Rite Aid knew of its obligations under federal and state law to prevent the diversion of controlled substances and to refrain from filling unlawful prescriptions.

7. Nevertheless, Rite Aid pharmacists repeatedly filled prescriptions for controlled substances that had obvious, and often multiple, red flags indicating misuse related to the prescription itself, the prescriber, the customer, or a combination of factors. Rite Aid pharmacists ignored these red flags, making either no effort or a patently inadequate effort to resolve the red flags.

8. Rite Aid pharmacists filled these unlawful prescriptions despite knowing, based on their training and experience, that they had a legal obligation not to fill them.

9. Moreover, Rite Aid, through its Government Affairs Department¹—which was responsible for ensuring Rite Aid’s compliance with federal and state laws—was aware that Rite Aid pharmacists filled prescriptions for controlled substances routinely and pervasively without actually resolving obvious red flags. While Rite Aid pharmacists were supposed to use a validation process for certain highly diverted controlled substances and to resolve red flags before dispensing, Rite Aid knew the validation process was a fig leaf. And Rite Aid knew that the validation process missed numerous other commonly diverted controlled substances,

¹ All references to “Government Affairs” throughout this Complaint include individuals reporting to the Senior Vice President of Regulatory Affairs but are referred to as “Government Affairs.”

including benzodiazepines and muscle relaxants, which form part of trinities, and stimulants like amphetamine combination products.

10. Further, despite their awareness that Rite Aid pharmacists were filling unlawful prescriptions, members of Rite Aid's Government Affairs Department disregarded: (1) concerns raised repeatedly by Rite Aid pharmacists about prescribers practicing outside the usual course of professional practice; (2) dispensing data and reports that showed problematic prescribing patterns behind the prescriptions Rite Aid filled; and (3) warnings from its distributor about the amount of drugs, in particular oxycodone, ordered for outlier Rite Aid stores.

11. Compounding these failures, Rite Aid's Government Affairs Department also repeatedly directed employees in another Rite Aid department to delete in Rite Aid's dispensing software Rite Aid pharmacists' internal notes about suspicious prescribers such as, "cash only pill mill???" "writing excessive dose[s] for oxycodone," and bluntly "DO NOT FILL CONTROLS." Instead of ensuring this vital information was available to all Rite Aid pharmacists, a Government Affairs analyst admonished a Rite Aid pharmacist who added such a note "to always be very cautious of what is put in writing."

12. Finally, even where Rite Aid's Government Affairs Department knew that a practitioner was not prescribing controlled substances for legitimate medical purposes through reports from its own pharmacists, Rite Aid very rarely took action to stop the flow of opioids prescribed by that practitioner. In fact, in the vast majority of the cases, the information languished in the Government Affairs Department with no action at all by Rite Aid.

13. As a result, Defendants failed to meet their obligations under the Controlled Substances Act (CSA), and instead put profits first, filling hundreds of thousands of prescriptions for controlled substances that did not meet legal requirements. Defendants likewise violated the

False Claims Act (FCA) by knowingly submitting, or causing to be submitted, false or fraudulent claims for such prescriptions to Federal Healthcare Programs. While making millions of dollars, Defendants opened the floodgates for millions of pills of opioids and other controlled substances to flow illegally out of their stores.

I. JURISDICTION AND VENUE

14. This action is brought by the United States under the FCA, the CSA, and common law.

15. This Court has subject matter jurisdiction over the FCA claims for civil damages and penalties pursuant to 31 U.S.C. § 3732, and 28 U.S.C. §§ 1331, 1345, and 1355.

16. This Court has subject matter jurisdiction over the CSA claims under 21 U.S.C. § 842(c)(1)(A), and 28 U.S.C. §§ 1331, 1345, and 1355.

17. This Court has subject matter jurisdiction over the common law claims pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

18. Venue is proper in the Northern District of Ohio as to the FCA claims and the common law claims against Defendants under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants Rite Aid Hdqtrs., Corp. and Rite Aid Corporation do business in this district, and Rite Aid of Ohio, Inc. is located, resides, and does business in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

19. Venue is proper in the Northern District of Ohio as to the CSA claims under 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants Rite Aid Hdqtrs., Corp. and Rite Aid Corporation do business in this district, and Rite Aid of Ohio, Inc. is located, resides, and does business in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

II. PARTIES

20. Plaintiff is the United States of America. Through its agencies, the United States administers healthcare programs for qualifying beneficiaries. More specifically, the U.S. Department of Health and Human Services (HHS) and its component, the Centers for Medicare and Medicaid Services (CMS), administer the Medicare and Medicaid programs, and the U.S. Department of Defense administers the TRICARE program. Collectively, the Medicare, Medicaid, and TRICARE programs will be referred to herein as the “Federal Healthcare Programs.”

21. Defendant Rite Aid Corporation is a publicly held Delaware corporation with its principal place of business in Philadelphia, Pennsylvania. Defendant Rite Aid Hdqtrs., Corp. is a wholly owned subsidiary of Defendant Rite Aid Corporation, also incorporated in Delaware with a principal place of business in Philadelphia, Pennsylvania. In addition, Defendant Rite Aid Corporation incorporated other wholly owned subsidiaries in each state where its pharmacies do business. In this action, these wholly owned subsidiaries are Defendants Rite Aid of Connecticut, Inc.; Rite Aid of Delaware, Inc.; Rite Aid of Maryland, Inc.; Rite Aid of Michigan, Inc.; Rite Aid of New Hampshire, Inc.; Rite Aid of New Jersey, Inc.; Rite Aid of Ohio, Inc.; Rite Aid of Pennsylvania, Inc.; and Rite Aid of Virginia, Inc. As noted above, all Defendants are collectively referred to throughout this Complaint as “Rite Aid,” except where otherwise specifically alleged.

22. As stated in Rite Aid Corporation’s Form 10-K for the fiscal year ending February 26, 2022, Rite Aid Corporation “deliver[s] health care services and retail products to over one million Americans daily.”

23. During all relevant times, Rite Aid, through its network of over 2,200 pharmacies in 17 states, has sold and continues to sell prescription drugs, including controlled substances, as one of the leading drugstore chains in the country.

24. Rite Aid reports its business into two distinct segments: (1) pharmacy services, consisting of its pharmacy benefits manager (PBM) business; and (2) retail pharmacy services, consisting of the retail pharmacy stores that make up the fourth largest retail pharmacy chain in the U.S. market. During Rite Aid Corporation's fiscal year 2022, prescription drug sales were \$12.2 billion, approximately 70% of its total drugstore sales. During fiscal year 2022, approximately 38.2% of Rite Aid Corporation's pharmacy sales were to customers covered by Medicare Part D, and approximately 18.2% of Rite Aid Corporation's pharmacy sales were to customers covered by Medicaid and related Medicaid managed care plans.

25. At all times relevant to this Complaint, Rite Aid operated stores with pharmacies that dispensed controlled substances to patients across the United States, and specifically in Connecticut, Delaware, Maryland, Michigan, New Hampshire, New Jersey, Ohio, Pennsylvania, and Virginia (referred to throughout as Rite Aid Stores). A list of the stores relevant to this Complaint is attached as Exhibit 1.

26. Each pharmacy identified in Exhibit 1 had its own Drug Enforcement Administration (DEA) registration number and National Provider Identifier (NPI) number in the name of the individual Rite Aid state entity where the pharmacy was located. Claims to Federal Healthcare Programs were submitted by the different Rite Aid state entities (Rite Aid of Connecticut, Inc.; Rite Aid of Delaware, Inc.; Rite Aid of Maryland, Inc.; Rite Aid of Michigan, Inc.; Rite Aid of New Hampshire, Inc.; Rite Aid of New Jersey, Inc.; Rite Aid of Ohio, Inc.; Rite Aid of Pennsylvania, Inc.; and Rite Aid of Virginia, Inc.), but all funds reimbursed by Federal

Healthcare Programs were paid to and maintained in a bank account held in the name of Rite Aid Hdqtrs., Corp.

III. LEGAL BACKGROUND

A. THE FALSE CLAIMS ACT AND FEDERAL HEALTHCARE PROGRAMS

1. The False Claims Act

27. The FCA provides, in part, that any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States Government for damages and penalties. 31 U.S.C. § 3729(a)(1)(A)-(B).

28. To show that a person acted “knowingly” under the FCA, the United States must prove that the person, with respect to information: (1) had actual knowledge of the information; (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information. The United States does not have to prove that the person had the specific intent to defraud. *Id.* § 3729(b)(1).

29. The FCA defines “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* § 3729(b)(4).

30. The FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of \$5,500 to \$11,000 per violation for violations that occurred on or before November 2, 2015, and, for violations that occurred after that date, a civil penalty of between \$13,508 and \$27,018. *Id.* § 3729(a)(1); 28 C.F.R. § 85.5.

2. Federal Healthcare Programs

a. Medicare Part D

31. Congress established the Medicare Program in 1965 to provide health insurance coverage for people aged 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a). Rite Aid presented, or caused to be presented, reimbursement claims under Medicare Part D.

32. Unlike the traditional fee-for-service Medicare program, Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan “Sponsors” to administer prescription drug plans. A Part D Plan Sponsor is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan, a Program of All-Inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

33. Part D Plan Sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D Plan Sponsors, in turn, enter into subcontracts with pharmacies or other downstream entities to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

34. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary’s Part D plan and receives reimbursement from the Part D

Plan Sponsor for the costs not paid by the beneficiary. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a Prescription Drug Event (PDE) record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

35. More specifically, when a customer brings a prescription to a Rite Aid pharmacy, a Rite Aid employee, either a pharmacy technician or a pharmacist, enters the prescription data into Rite Aid's dispensing system, called NexGen. Rite Aid also collects the customer's insurance card or, for existing customers, uses existing insurance information on file. Rite Aid submits prescription and insurance information to the third-party payer (either commercial insurance or a Federal Healthcare Program) through what is known as a "switch." A switch is a third-party software vendor that transmits requests from pharmacies.

36. Rite Aid primarily uses two switches to route claims to the insurance plan or Federal Healthcare Program. The switch determines which payer receives the request. Upon receipt of the request, the payer informs the switch of the customer's co-pay amount, and then the switch relays this information back to the Rite Aid pharmacy.

37. Each PDE that is submitted to CMS by a Part D Plan Sponsor is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and is used to reconcile payments to a Part D Plan Sponsor. The data contained in PDEs are data related to payment of claims.

38. Submitting PDE claims data to CMS, which is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors for qualified drug coverage, is a material condition of payment for CMS's provision of Medicare funds to Part D Plan Sponsors. *See* 42 C.F.R. § 423.322.

39. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

40. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

41. CMS also makes payments to the Part D Plan Sponsor for premium and cost-sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost-Sharing Subsidies" and are documented and reconciled using PDE data submitted to CMS.

42. The reinsurance subsidy is paid to the Part D Plan Sponsor to cover the Government's share of drug costs above an enrollee's catastrophic threshold.

43. Part D Plan Sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2), (d)(2). In addition, Part D Plan Sponsors are responsible for correcting submitted PDE data that they determine are erroneous. *See* CMS, UPDATED INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA (PDE) at 22 (Apr. 27, 2006).

44. After the close of the plan year, CMS is responsible for reconciling the Part D Plan Sponsor's prospective payments to its actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records. *See generally id.* After CMS reconciles a plan's prospective payments and actual allowable costs, CMS then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

45. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws and regulations, as well as CMS instructions.

46. By statute, all contracts between a Part D Plan Sponsor and HHS must include a provision whereby the Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

47. Medicare Part D Plan Sponsors also must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1).

48. Regulations further require that all subcontracts between Part D Plan Sponsors and downstream entities (including PBMs and pharmacies like Rite Aid) must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. *Id.* § 423.505(i)(4)(iv). Defendant Rite Aid Corporation executed such agreements on behalf of itself and its pharmacies.

49. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness, and truthfulness of all data related to the payment. This provision, entitled “Certification of data that determine payments,” provides in relevant part, as follows:

(1) General rule. ***As a condition for receiving a monthly payment . . . the Part D plan sponsor agrees that*** its chief executive officer (CEO), chief financial officer (CFO), or ***an individual*** delegated the authority to sign on behalf of one of these officers . . . ***must request payment under the contract on a document that certifies*** (based on best knowledge, information, and belief) the ***accuracy, completeness, and truthfulness*** of all data related to payment....

(3) [Part D Sponsor] Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information, and belief) that the claims data it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

Id. § 423.505(k)(1), (k)(3) (emphasis added).

50. All approved Part D Plan Sponsors that received payment under Medicare Part D in benefit years relevant to this Complaint submitted the required attestations for data submitted that related to payment. *Id.* § 423.505(k).

51. The “Certification of data that determine payments” provision of the applicable regulation further provides: “[i]f the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.” *Id.* § 423.505(k)(3).

52. Compliance with the requirement that PDE data submitted by the Part D Plan Sponsor is “accurate, complete, and truthful” based on best knowledge, information, and belief, is a condition of payment to the Sponsor under the Medicare Part D Program. *Id.* § 423.505(k)(2). Compliance also is material to payment.

53. Medicare covers only drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. §1395w-102(e)(1), (e)(4); *Id.* § 1396r-8(g)(1)(B)(i), (k)(6); 42 C.F.R. § 423.100.

54. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as recreational use, are not for “medically accepted indications” and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1), (e)(4).

55. In addition, Medicare only covers drugs that are dispensed upon a valid prescription. *Id.* § 1395w-102(e); 42 C.F.R. § 423.100. “A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.” 42 C.F.R. § 423.104(h). A valid prescription must comply “with all applicable State law requirements constituting a valid prescription.” *Id.* § 423.100.

56. States set forth these requirements by statute and regulation. Connecticut has a catch-all requirement that “prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, [and] the federal Controlled Substances Act” CONN. GEN. STAT. ANN. § 21a-249(f).

57. Delaware mandates that prescriptions for controlled substances be issued only by practitioners who are authorized to do so by the jurisdiction in which they practice and are registered or exempt from registration in Delaware. 24 DEL. ADMIN. CODE § 4.1.1.1-2. Further, all prescriptions for controlled substances “must be issued for a legitimate medical purpose by practitioner acting in the usual course of their professional practice.” *Id.* § 4.2.1.

58. Maryland requires that controlled substances be dispensed only pursuant to a prescription. MD. CODE ANN., HEALTH-GEN. § 21-220. Prescription is separately defined as “an order by a prescriber, or a prescriber’s order transferred from one pharmacist to another, for Program covered pharmacy services in accordance with applicable federal and State laws conveyed in” a specified form. MD. CODE REGS. § 10.09.03.01(B)(37). Furthermore, the prescription must be deemed valid in the professional judgment of the pharmacist filling the prescription. *Id.* § 10.34.20.02(A).

59. Michigan requires that practitioners prescribe controlled substances in “good faith,” which is defined as “in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual’s physical or psychological dependence on or addiction to a controlled substance” MICH. COMP. LAWS ANN. § 333.7333(1).

60. New Hampshire defines a prescription as “an oral, written, or facsimile or electronically transmitted order for any controlled drug or preparation issued by a licensed practitioner to be compounded and dispensed by a pharmacist and delivered to a patient for a medicinal or therapeutic purpose arising from a practitioner-patient relationship.” N.H. REV. STAT. ANN. § 318-B:1(XXVIII).

61. New Jersey states that “[a] practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient’s condition, may issue a written prescription for a drug to a patient” N.J. ADMIN. CODE § 13:35-7.2(a).

62. To qualify as a “valid prescription” in Ohio, the prescription for a controlled substance must be made by “[a] licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the

professional's practice, and in accordance with the rules adopted by the state board of pharmacy" OHIO REV. CODE ANN. § 3719.06(A)(1). "A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice." OHIO ADMIN. CODE 4729-5-30 (rescinded) (current version at OHIO ADMIN. CODE 4729:5-5-15(A)).

63. In Pennsylvania, "[a] practitioner may prescribe, administer, or dispense a controlled substance or other drug or device only (i) in good faith in the course of his professional practice, (ii) within the scope of the patient relationship, and (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession." 35 PA. STAT. AND CONS. STAT. § 780-111(d).

64. In Virginia, a "valid prescription" may be issued only by a prescriber who is authorized to prescribe controlled substances, as set forth in VA. CODE ANN. § 54.1-3303(A). The prescriber must have a bona fide practitioner-patient relationship. *Id.* § 3303(B). "A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription." *Id.* § 3303(C).

65. PDEs submitted to Medicare for controlled substances that are not for medically accepted indications and/or are not based on valid prescriptions do not contain accurate, complete, and truthful information about all data related to payment.

b. Medicaid

66. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily for low-income and disabled patients. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specific minimum criteria for coverage and payment

of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

67. As with Medicare, Medicaid coverage extends only to “prescribed drugs,” and does not include drugs dispensed pursuant to invalid prescriptions. *See id.* § 1396d(a)(12).

68. The federal portion of each state’s Medicaid payments, known as the Federal Medical Assistance Percentage (FMAP), is based on the state’s per capita income compared to the national average. *Id.* § 1396d(b). Among the states, the FMAP is at least fifty percent and is as high as eighty-three percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the “total amount expended . . . as medical assistance under the State plan.” *Id.* § 1396b(a)(1).

69. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for any adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

70. Providers, like Rite Aid, who participate in the Medicaid program must sign enrollment agreements with these states that certify compliance with the state and federal Medicaid requirements. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that the provider will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

71. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations. In Ohio, for example, providers, including pharmacies like Rite Aid, certify in provider applications and revalidation applications that they will “comply with the terms of this provider agreement, Ohio statutes, Ohio Administrative Code rules, and Federal statutes and rules,” and further certify that they will render only “medically necessary” services.

c. TRICARE

72. TRICARE (formerly known as CHAMPUS) is part of the United States military’s healthcare system, designed to maintain the health of active-duty service personnel, provide healthcare during military operations, and offer healthcare to non-active-duty beneficiaries, including dependents of active-duty personnel, and military retirees and their dependents. The military health system, which is administered by the U.S. Department of Defense, is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE contracts with PBMs to administer its retail and mail order pharmacy programs.

73. TRICARE will pay only “for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. . . . However,

TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.” 32 C.F.R. § 199.4(e)(11).

74. When a TRICARE beneficiary’s drug prescription is submitted to a TRICARE network pharmacy like Rite Aid, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary’s TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a ten-day hold to ensure the prescription medication is delivered to the patient (and not returned to the shelf by the pharmacy), the PBM sends a TRICARE Encounter Data (TED) record electronically to TRICARE. The TED record includes information regarding the prescription event, including the prescriber’s identity, the date the prescription was written, the number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under TRICARE.

75. TRICARE authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim, and the PBM sends the payment to the pharmacy. As a fiscal intermediary for the Government, the PBM is authorized to disburse government funds for health care benefits and receives reimbursement for such funds from the Federal Reserve Bank.

76. All pharmacies that provide services to TRICARE beneficiaries are required to comply with TRICARE’s program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE’s

anti-abuse provisions can be denied. *Id.* § 199.9(b). Billing for costs for non-covered services is included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(2).

77. As a direct, proximate, and foreseeable result of Rite Aid's dispensing of controlled substances without valid prescriptions, for medically unnecessary uses and not for medically accepted indications, Rite Aid caused claims to be submitted to Federal Healthcare Programs and made or caused statements to be made that were material to such claims.

B. THE CONTROLLED SUBSTANCES ACT

78. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. Congress enacted the CSA to facilitate the availability of controlled substances for authorized medical use, while also preventing controlled substances from being diverted out of legitimate channels for illegal purposes. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1).

79. Under the CSA, controlled substances are categorized into five schedules based on several factors, including the substance's medical use, potential for abuse, and the likelihood they will cause dependence if abused.

80. The prescription drugs at issue in this Complaint are found in schedules II, III, IV, and V.

81. Schedule II contains drugs with "a high potential for abuse" that, if abused, "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Examples of schedule II controlled substances relevant to this Complaint include oxycodone (*e.g.*, brand name OxyContin),

oxymorphone (brand name Opana), morphine sulfate (*e.g.*, brand name MS Contin), dextroamphetamine-amphetamine (*e.g.*, brand name Adderall), methadone, and fentanyl.

82. Schedule III contains drugs with less abuse potential than those in schedule II but which, if abused, “may lead to moderate or low physical dependence or high psychological dependence.” *Id.* § 812(b)(3). Schedule III drugs also have “a currently accepted medical use in treatment.” *Id.* Examples of schedule III controlled substances relevant to this Complaint include containing buprenorphine (*e.g.*, brand name Suboxone).

83. Schedule IV contains drugs that, although having a lower abuse potential than schedule III drugs, still may lead to physical or psychological dependence when abused but have “a currently accepted medical use in treatment.” *Id.* § 812(b)(4). Examples of schedule IV controlled substances relevant to this Complaint include alprazolam (*e.g.*, brand name Xanax), diazepam (*e.g.*, brand name Valium), zolpidem (*e.g.*, brand name Ambien), and carisoprodol (brand name Soma).

84. Schedule V contains drugs that, although having a lower abuse potential than schedule IV drugs, still may lead to physical or psychological dependence when abused but have “a currently accepted medical use in treatment.” *Id.* § 812(b)(5). An example of a schedule V controlled substance relevant to this Complaint is pregabalin (brand name Lyrica).

85. The CSA requires pharmacies that distribute or dispense controlled substances to obtain a registration from the DEA. *Id.* § 822(a). A registered pharmacy is permitted to distribute or dispense controlled substances only “to the extent authorized by their registration and in conformity with” the CSA. *Id.* § 822(b).

86. Pharmacies may be registered to “dispense” controlled substances in schedule II through V. *Id.* § 823(f). The CSA defines dispensing to mean delivering a controlled substance

to an ultimate user (*e.g.*, a patient) by, or pursuant to a lawful order of, a practitioner (*i.e.*, a prescription). *See id.* § 802(10).

87. The agents and employees of a dispenser of controlled substances are not required to have a separate DEA registration “if such agent or employee is acting in the usual course of his business or employment.” *Id.* § 822(c)(1). Rite Aid employed pharmacists, who dispensed controlled substances on behalf of Rite Aid as agents and employees.

88. Under the CSA, except in emergency situations, pharmacies cannot dispense a schedule II controlled substance to an ultimate end user without the written prescription of a practitioner, such as a physician. *Id.* § 829(a). Pharmacies cannot dispense schedule III or IV controlled substances to an ultimate end user without a written or oral prescription from a practitioner. *Id.* § 829(b). Schedule V controlled substances may be distributed or dispensed only for a medical purpose. *Id.* § 829(c).

89. A prescription (written or oral) is legally valid under the CSA only if issued for “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). “An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent” of 21 U.S.C. § 829, and “the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” *Id.* “Person” is defined to include an individual, a corporation, a partnership, an association, and any other legal entity. *Id.* § 1300.01.

90. “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” *Id.* § 1306.04(a).

IV. RITE AID KNOWINGLY FILLED UNLAWFUL PRESCRIPTIONS AND SUBMITTED FALSE OR FRAUDULENT CLAIMS

91. From at least May 1, 2014 through June 10, 2019, Rite Aid filled at least hundreds of thousands of unlawful prescriptions for controlled substances (schedules II through V) at the Rite Aid Stores listed in Exhibit 1. Rite Aid filled these prescriptions knowing, at least with willful blindness, that these controlled substances were medically unnecessary and unlawful because the prescriptions (1) had red flags, often multiple ones, that Rite Aid had identified internally as indicating a prescription was unlawful and that pharmacists knew from training and experience were highly indicative that a prescription was unlawful; and (2) were often also issued by prescribers who, based on information from its own pharmacists and members of Rite Aid's Government Affairs Department, Rite Aid knew to be suspicious and to issue unlawful prescriptions to patients. Rather than comply with its legal obligation to ensure that these prescriptions were legitimate, Rite Aid Stores filled these prescriptions and, where the customer had insurance through a Federal Healthcare Program, sought reimbursement from the government.

A. RITE AID FILLED UNLAWFUL CONTROLLED SUBSTANCE PRESCRIPTIONS

92. Rite Aid filled prescriptions for controlled substances that were unlawful because they (1) lacked a legitimate medical purpose and were not issued in the usual course of professional practice, in violation of the CSA; and (2) were not valid prescriptions, were not for a medically accepted indication, and/or were medically unnecessary, in violation of Federal Healthcare Programs' material requirements for payment.

93. These unlawful prescriptions had clear red flags, many of which highly indicated that the prescription was unlawful and which Rite Aid directed its pharmacists to assess and resolve through its dispensing protocol. Examples of these red flags include:

- a. Prescriptions for the trinity combination;
- b. Prescriptions for excessive quantities of controlled substances, including, but not limited to, overlapping prescriptions for combinations of controlled substances other than the trinity;
- c. Prescriptions for a fill or refill of any controlled substance prescription sooner than 48 hours before the prior prescription's due date (for prescriptions since June 2016);
- d. Prescriptions of controlled substances for patients receiving multiple controlled substance prescriptions from multiple prescribers;
- e. Prescriptions for patients receiving a controlled substance for more than twelve consecutive weeks; and
- f. Prescriptions for patients receiving only prescriptions for controlled substances and/or prescriptions for the trinity.

94. The government issued warnings that prescriptions containing some of these red flags posed serious health risks. On August 31, 2016, for example, the U.S. Food and Drug Administration (FDA) added its strongest warning to opioids and benzodiazepines prescribed together, in an effort to decrease these combinations after an FDA review found that taking opioids with benzodiazepines, which depress the central nervous system, resulted in difficulty breathing and death.

95. Rite Aid itself acknowledged that many of these red flags were indicative of abuse or diversion. For example, discussing the trinity in a June 7, 2016, declaration filed in the state court litigation alleged *infra* in Paragraph 128, Janet Hart, Rite Aid's Director of Government Affairs, stated that "the DEA has stated at numerous Diversion Awareness

Conferences throughout the country that there is no medical need to have these three drugs prescribed at the same time.”

96. The following are representative examples of controlled substances dispensed by Rite Aid pursuant to unlawful prescriptions that (1) had these red flags, often multiple red flags; and/or (2) were issued by prescribers who, based on information from Rite Aid pharmacists, Rite Aid’s Government Affairs Department knew were acting outside the usual course of professional practice and issuing unlawful prescriptions.

97. For each prescription reimbursed by Medicare, Defendants caused PDE data to be submitted to CMS for the listed prescription and CMS made payments in reliance on this PDE data. The prescriptions were ineligible under Federal Healthcare Programs because they were not dispensed consistent with federal law. The PDE data was false, inaccurate, and incomplete. Defendants caused the false claims to be submitted and in turn caused CMS to make payments for the drugs. Similarly, Defendants submitted, or caused to be submitted, data to TRICARE and the state Medicaid programs that was false, inaccurate, and incomplete, and Defendants caused those programs to make payments for the prescription drugs.

1. Prescriptions for the Trinity

98. Rite Aid dispensed numerous prescriptions for the trinity, which is a combination of prescription drugs including an opioid (*e.g.*, oxycodone), a benzodiazepine (*e.g.*, alprazolam), and a muscle relaxant (*e.g.*, carisoprodol) or stimulant. It is widely acknowledged to be highly abused and dangerous. Drug abusers seek it out for the increased euphoric effect that occurs when taking these three controlled substances together.

99. For example, on or about February 8, 2017, Rite Aid Store No. 00277 in Ohio filled prescriptions written by Prescriber S.W. for Patient T.M. for hydrocodone-acetaminophen 5-325 milligrams (20 tablets), carisoprodol 350 milligrams (15 tablets), and alprazolam .5

milligrams (15 tablets). The Rite Aid pharmacist expressly noted on the hard copy prescriptions, as shown below, that this combination is a trinity, but filled them anyway. The pharmacist did so despite apparently discussing them with Prescriber S.W., a physician assistant, who justified the prescriptions by saying the doses were “low” and being monitored. There is no indication of the patient’s diagnosis on the prescriptions or from the pharmacist’s written notes.

P.D.
Discussed with [redacted]
about trinity - Dose is
low and she is monitoring
8 Feb 17
1410

[redacted]

Patient Name: [redacted] DOB: [redacted]
Gender: [redacted]

MRN:
Acct#: 1295

Date: 02/08/2017

R_x

SIG: hydrocodone-acetaminophen 5-325 mg tablet, 7 days, Dispense #20 Tablet, 0 Refills
Directions: Take 1 oral tablet 3 times a day, prn
Substitution Allowed
Type: Routine
Pharmacist: Use this information for uninsured patients.
ID:740-499-2663 rxBIN:016151 PCN:BNRX GRP:AMD

[redacted]

Electronically Signed
Substitution Allowed

twenty

Discussed & [redacted] about Trinity
- Low dose
- is monitoring
- [redacted] Kiv 8 Feb 16 1410

Patient Name: [redacted] ID: [redacted]
DOB: [redacted]
Gender: [redacted]
MRN: [redacted]
Acct#: 1295

Date: 02/08/2017

R_x SIG: carisoprodol 350 mg tablet, 15 days, Dispense #15 Tablet, 0 Refills
Directions: take 1 tablet by mouth at bedtime *after*
Substitution Allowed
Type: Routine
Pharmacist: Use this information for uninsured patients.
ID:740-499-2663 rxBIN:016151 PCN:BNRX GRP:AMD

[redacted]
Electronically Signed
Substitution Allowed

Discussed & [redacted] about Trinity
- Doses Low
- is monitoring
- [redacted] Kiv 8 Feb 17 1410

Patient Name: [redacted] ID: [redacted]
DOB: [redacted]
Gender: [redacted]
MRN: [redacted]
Acct#: 1295

Date: 02/08/2017

R_x SIG: alprazolam 0.5 mg tablet, 15 days, Dispense #15 Tablet, 0 Refills
Directions: Take 1 oral tablet once a day as needed *after*
Substitution Allowed
Type: Routine
Pharmacist: Use this information for uninsured patients.
ID:740-499-2663 rxBIN:016151 PCN:BNRX GRP:AMD

[redacted]
Electronically Signed
Substitution Allowed

100. These prescriptions had no legitimate medical purpose and were outside the usual course of professional practice. Filling them was therefore improper and in direct conflict with

Rite Aid's acknowledgement that there is no medical need for prescribing these drugs at the same time.

101. In August 2017, an internal Rite Aid corporate review conducted for fills in June 2017 found over 1,000 patients filled prescriptions for an opioid, benzodiazepine, and muscle relaxant at the same time during that month alone.

102. Further examples of trinity prescriptions Rite Aid filled are set forth below, which include examples of prescriptions filled on the same day and prescriptions filled over the course of several days.

RX #	Patient	Prescriber	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
1215534	VB	MP	10/25/2016	10/30/2016	Alprazolam	1 MG	01433	Ohio Medicaid	\$2.87
1215542	VB	MP	10/25/2016	10/26/2016	Carisoprodol	350 MG	01433	Ohio Medicaid	\$2.96
1215543	VB	MP	10/25/2016	10/27/2016	Oxycodone HCL ER	10 MG	01433	Ohio Medicaid	\$136.75
1215546	VB	MP	10/25/2016	10/25/2016	Oxycodone HCL	5 MG	01433	Ohio Medicaid	\$10.98
1270508	SP	HP	2/23/2016	5/25/2016	Carisoprodol	350 MG	00277	Ohio Medicaid	\$5.77
1270510	SP	HP	2/23/2016	5/4/2016	Alprazolam	1 MG	00277	Ohio Medicaid	\$2.25
1296598	SP	HP	5/3/2016	5/12/2016	Hydrocodone -Acetamin	5-325 MG	00277	N/A	N/A
1246454	SP	HP	12/15/2015	1/13/2016	Alprazolam	1 MG	00277	Ohio Medicaid	\$1.84
1252729	SP	HP	12/8/2015	1/7/2016	Carisoprodol	350 MG	00277	Ohio Medicaid	\$7.15
1255780	SP	HP	1/14/2016	1/14/2016	Hydrocodone -Acetamin	5-325 MG	00277	N/A	N/A
306113	AB	E-JK	6/5/2017	6/6/2017	Opana ER	40 MG	06681	Medicare	\$1276.07
306117	AB	E-JK	6/5/2017	6/6/2017	Alprazolam	1 MG	06681	Medicare	\$6.26
306115	AB	E-JK	6/5/2017	6/6/2017	Carisoprodol	350 MG	06681	Medicare	\$8.42
306114	AB	E-JK	6/5/2017	6/6/2017	Oxycodone-Acetaminophen	10-325 MG	06681	Medicare	\$58.99

RX #	Patient	Prescriber	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
1438715	DS ²	MB	9/23/2014	9/25/2014	Morphine Sulfate ER	15 MG	00347	Medicare	\$28.59
1438722	DS	MB	9/23/2014	9/25/2014	Oxycodone HCL	10 MG	00347	Medicare	\$17.62
1440320	DS	AH	9/30/2014	9/30/2014	Diazepam	10 MG	00347	Medicare	\$3.51
1450565	DS	MB	9/23/2014	9/25/2014	Carisoprodol	350 MG	00347	Medicare	\$25.39
911642	DR	CB	7/10/2017	7/14/2017	Lorazepam	1 MG	04144	Medicare	\$2.28
913382	DR	CB	7/24/2017	7/27/2017	Oxycodone HCL	30 MG	04144	Medicare	\$59.60
911641	DR	CB	7/10/2017	7/27/2017	Carisoprodol	350 MG	04144	Medicare	\$8.53
911642	DR	CB	7/10/2017	8/19/2017	Lorazepam	1 MG	04144	Medicare	\$2.35
917497	DR	CB	8/22/2017	8/24/2017	Oxycodone HCL	30 MG	04144	Medicare	\$62.56
911641	DR	CB	7/10/2017	8/24/2017	Carisoprodol	350 MG	04144	Medicare	\$8.77
918111	DR	CB	8/27/2017	8/27/2017	Lorazepam	1 MG	04144	Medicare	\$5.49
920983	DR	CB	9/18/2017	9/21/2017	Carisoprodol	350 MG	04144	Medicare	\$8.77
920982	DR	CB	9/18/2017	9/21/2017	Oxycodone HCL	30 MG	04144	Medicare	\$62.56
918111	DR	CB	8/27/2017	9/25/2017	Lorazepam	1 MG	04144	Medicare	\$5.49

103. Each of the controlled substances listed in the chart is a prescription drug under the FDCA. These prescriptions were filled by Rite Aid Stores that had DEA registration numbers and NPI numbers in the name of the individual Rite Aid state entity where the store was located (*i.e.*, Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc., Rite Aid of New Hampshire, Inc.). The reimbursements for these prescriptions were sent into an account in the name of Rite Aid Hdqtrs., Corp. Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and the associated Rite Aid state entities knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice. The claims for prescriptions listed as reimbursed by Federal Healthcare

² Rite Aid's internal dispensing software included the words "(CHECK ID)" in the data field for this patient's name.

Programs were false because they were not valid prescriptions, were not for a medically accepted indication, and/or were not medically necessary.

2. Prescriptions for Excessive Quantities and Prolonged Periods

104. Rite Aid Stores also filled prescriptions for excessive quantities of controlled substances and prescriptions for patients receiving a controlled substance for more than twelve consecutive weeks.

105. For example, Prescriber Gary Frantz issued prescriptions to patient C.F. dated March 14, 2014 for oxycodone 30 mg tablets. The prescription was for 780 tablets, 78 tablets a day. The prescription notes that only 372 tablets were filled as that was "all I had."

Mansfield Family Practice
[Redacted] MD
LIC #: [Redacted] • DEA #: [Redacted]
NPI #: [Redacted]
MANSFIELD, OH 449032306
Tel: (419) 524-2212 • Fax: (419) 524-9040

SIG

NAME [Redacted] SEX Male AGE 37 DOB [Redacted]
ADDRESS [Redacted] MANSFIELD, OH 44903 DATE 03/14/2014

Rx
oxycodone 30 mg tablet
Disp: 780 (seven hundred eighty) Tablet
Sig: 13 tabs po q4hr- 78 tabs a day
Start Date: 03/17/2014
Stop Date: 03/26/2014

COMMENTS
May fill 3 days prior to fill date.
Syndrome of Lumbar Spine
Postlaminectomy Pain

372
Filled 372 (all I had)

1-24
25-49
50-74
75-100
101-150
151 and over

QARRS 3/15/14
okay on fill date

Refill _____ times PRN (NR)

Signature: [Redacted] MD

106. Frantz continued to write these high-dose prescriptions to patient C.F. For example, on May 3, 2017, Frantz wrote, and Rite Aid filled on May 11, 2017, a prescription for 30 fentanyl 50 microgram per hour transdermal patches; C.F. was to apply two patches every 48 hours.

Rx 30 4836

OhioHealth Primary Care Physicians
[REDACTED] MD
LIC #: [REDACTED] • DEA #: [REDACTED]
NPI #: [REDACTED]
[REDACTED]
MANSFIELD, OH 449032306
Tel: (419) 524-2212 • Fax: (419) 524-9040

NAME [REDACTED] SEX Male AGE 40 DOB [REDACTED]
ADDRESS [REDACTED] MANSFIELD, OH 44903 DATE 05/03/2017

Rx
fentanyl 50 mcg/hr transdermal patch
Disp: 30 (thirty) Patch

Sig: apply 2 patch by transdermal route every 48 hours
Start Date: 05/06/2017
Stop Date: 06/04/2017

COMMENTS
May fill 3 days before start date. For Pain of Lumbar Postlaminectomy Pain Syn.
[REDACTED]

[REDACTED]

[REDACTED]

Refill _____ times PRN (NR)

Signature: _____ MD

107. Yet Frantz was still prescribing, and Rite Aid was still filling, oxycodone to C.F. For example, on May 3, 2017, Frantz wrote a prescription that Rite Aid filled on May 11, 2017 for 231 oxycodone 30 milligram tablets, 5.5 tablets every four hours.

RT 304834

OhioHealth Primary Care Physicians
[REDACTED], MD
LIC #: [REDACTED] • DEA #: [REDACTED]
NPI #: [REDACTED]
[REDACTED]
MANSFIELD, OH 449032306
Tel: (419) 524-2212 • Fax: (419) 524-9040

NAME [REDACTED] SEX Male AGE 40 DOB [REDACTED]
ADDRESS [REDACTED] MANSFIELD, OH 44903 DATE 05/03/2017

R
oxycodone 30 mg tablet
Disp: 231 (two hundred thirty-one) Tablet
Sig: Week 109 - 5.5 tabs po q4hr
Start Date: 05/13/2017
Stop Date: 05/19/2017

COMMENTS
May fill 3 days before start date. Postlaminectomy Pain Syndrome of Lumbar Spine.

REASON FOR MEDICATION
DX Code: 338.4 Chronic pain syndrome
DX Code: 722.83 Postlaminectomy syndrome of lumbar region
[REDACTED]

Refill _____ times PRN (NR)

Signature: [REDACTED] _____, MD

1-24
25-49
50-74
75-100
101-160
151 and

Chronic Pain 7/14/16

108. Both Frantz and patient C.F. were indicted in the Northern District of Ohio in August 2019, in a 242-count indictment alleging conspiracy to distribute and dispense controlled substances and distribution of controlled substances. *United States v. Frantz*, Case No. 1:19-cr-00489. Both defendants ultimately pleaded guilty, patient C.F. to three counts and Frantz to ten counts.

109. As the United States described in its sentencing memorandum, the amount of schedule II controlled substances that Frantz prescribed to C.F. was forty-four times the

recommended standard, and the government's expert witness described the amounts as "'above those required during major surgery and for severe cancer pain.'" *Id.*, Doc#: 179, PageID# 2784.

110. Patient C.F. also was diverting some of the prescriptions to other customers. C.F. was able to both take and sell a significant amount of controlled substances because Frantz was writing prescriptions for such excessive amounts of controlled substances.

111. Rite Aid also filled unlawful prescriptions issued by Prescriber William Bauer, see *infra* Paragraph 125.d. These included prescriptions for excessive quantities of controlled substances that Bauer wrote for patient J.S. for more than eleven years. This was far in excess of any medically necessary amount, as well as Rite Aid's red flag of twelve consecutive weeks.

112. For example, Bauer wrote overlapping prescriptions for controlled substances between October and December of 2018 for patient J.S. for excessive quantities as follows:

- a. On October 23, 2018: oxycodone 40 mg oral tablet, 90 tablets, due November 27, 2018;
- b. On October 23, 2018: oxycodone 15 mg oral tablet, 120 tablets, due December 1, 2018;
- c. On October 23, 2018: oxycodone 40 mg oral tablet, 90 tablets, due December 27, 2018;
- d. On October 23, 2018: oxycodone 15 mg oral tablet, 120 tablets, due December 31, 2018;
- e. On October 23, 2018: oxycodone 40 mg oral tablet, 90 tablets, due January 26, 2019;
- f. On October 23, 2018: oxycodone 15 mg oral tablet, 120 tablets, due January 30, 2019;

- g. On November 14, 2018: methadone 5 mg oral tablet, 90 tablets, due November 14, 2018;
- h. On December 11, 2018: diazepam 5 mg oral tablet, 90 tablets with three refills, due December 11, 2019; and
- i. On December 11, 2018: Lyrica 100 mg oral capsule, 90 capsules with two refills, due December 19, 2018.

113. Bauer was indicted in August 2019 and convicted in July 2021 of 101 counts of distribution of controlled substances and health care fraud, including for the prescriptions Bauer issued to patient J.S. *United States v. Bauer*, Case No. 3:19-cr-00490-JZ, Doc #147. He was later sentenced to five years in prison.

114. Bauer knew that patient J.S. had attempted suicide eight times. *Id.*, Doc #162, PageID #2035-37. Four of those attempts were overdoses on prescribed controlled substances. *Id.*

115. Bauer prescribed controlled substances, including opioids, to patient J.S. “in support of dependency and addiction, and not for a legitimate medical purpose[.]” as the government’s medical expert testified at trial. *Id.* at PageID# 2041.

116. Each of these controlled substances alleged above is a prescription drug under the FDCA. These prescriptions were filled by Rite Aid Stores that had DEA registration numbers and NPI numbers in the name of Rite Aid of Ohio, Inc. The reimbursements for these prescriptions were sent into an account in the name of Rite Aid Hdqtrs., Corp. Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and Rite Aid of Ohio, Inc. knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice.

3. Prescriptions for Patients Receiving Only Controlled Substances or Trinity Prescriptions and for Early Fills

117. Rite Aid Stores also filled unlawful prescriptions for patients who received only controlled substances and/or trinity combinations and for patients sooner than Rite Aid Stores should have.

118. For example, Rite Aid Store 00789 in New Jersey filled only controlled substances for Patient K.H., totaling at least 76 prescriptions and overwhelmingly for the powerful, synthetic opioid fentanyl. These controlled substance prescriptions were issued by at least two prescribers, including Prescribers V.M. and L.S. In 2016, the State of New Jersey suspended Prescriber V.M.'s license for professional misconduct based on V.M.'s prescribing of fentanyl and, in 2018, revoked V.M.'s license. In 2017, the State of New Jersey temporarily banned Prescriber L.S. from treating patients based on the prescribing of fentanyl. Moreover, Rite Aid pharmacists reported L.S. to the Government Affairs Department at least twice, and a Government Affairs analyst reviewed L.S.'s prescribing multiple times beginning as early as 2014 but took no action. Examples of fentanyl prescriptions issued by Prescriber L.S. to Patient K.H. and filled by Rite Aid Store 00789 include:

- a. On December 12, 2016: fentanyl 100 micrograms per hour, 30 day supply, reimbursed by New Jersey Medicaid in the amount of \$102.21;
- b. On January 9, 2017: fentanyl 100 micrograms per hour, 30 day supply, reimbursed by New Jersey Medicaid in the amount of \$120.89; and
- c. On February 6, 2017: fentanyl 100 micrograms per hour, 30 day supply, reimbursed by New Jersey Medicaid in the amount of \$112.14.

119. Representative examples of unlawful prescriptions filled early are set forth in the table below. These include multiple prescriptions with at least 30 days supply for the same

combination of oxycodone 30 mg, which is widely diverted, and an amphetamine filled early and in increasing quantities for Patient F.N. and multiple prescriptions with at least 30 days supply for fentanyl for Patient T.S.:

RX #	Patient	Prescriber	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
739920	FN	BR	1/17/2018	1/17/2018	Oxycodone Hcl	30MG	01576	Medicare	\$23.51
740166	FN	BR	1/17/2018	1/17/2018	Dextroamphetamine-Amphetamine	30MG	01576	Medicare	\$23.33
742551	FN	LB	2/13/2018	2/13/2018	Oxycodone Hcl	30MG	01576	Medicare	\$21.93
742552	FN	LB	2/13/2018	2/13/2018	Dextroamphetamine-Amphetamine	30MG	01576	Medicare	\$23.33
1016568	TS	DH	8/31/2017	9/1/2017	Fentanyl	50MCG /HR	04916	DE Medicaid	\$170.03
1019313	TS	MA	9/15/2017	9/27/2017	Fentanyl	50MCG /HR	04916	DE Medicaid	\$261.29

120. Each of the controlled substances listed in Paragraph 118 and the chart above is a prescription drug under the FDCA. These prescriptions were filled by Rite Aid Stores that had DEA registration numbers and NPI numbers in the name of the individual Rite Aid state entity where the store was located (*i.e.*, Rite Aid of Michigan, Inc., Rite Aid of Delaware, Inc., and Rite Aid of New Jersey, Inc.). The reimbursements for these prescriptions were sent into an account in the name of Rite Aid Hdqtrs., Corp. Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and the associated Rite Aid state entities knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice. The claims for prescriptions listed as

reimbursed by Federal Healthcare Programs were false because they were not valid prescriptions, were not for a medically accepted indication, and/or were not medically necessary.

4. Controlled Substance Prescriptions Issued by Multiple Prescribers

121. Rite Aid Stores also filled unlawful prescriptions for controlled substances for the same patient issued by multiple prescribers. Representative examples are set forth below for Patient T.S., who received prescriptions for controlled substances, including fentanyl and oxycodone, from at least five prescribers as shown below and in two prescription examples in the early fill table *supra*, and for Patient S.T., who received prescriptions for oxycodone-acetaminophen from at least three prescribers over one month, one of whom was in Michigan although the patient and the Rite Aid Store where the prescription was filled were in Virginia:

RX #	Patient	Prescriber	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
857050	TS	ZJ	7/31/2015	11/30/2015	Diazepam	10 MG	04916	DE Medicaid	\$1.21
857050	TS	ZJ	7/31/2015	12/27/2015	Diazepam	10 MG	04916	DE Medicaid	\$2.42
894122	TS	ZJ	1/25/2016	1/25/2016	Diazepam	10 MG	04916	DE Medicaid	\$1.53
894799	TS	DS-D ³	1/28/2016	2/4/2016	Kadian ER	60 MG	04916	DE Medicaid	\$1097.19
894800	TS	DS-D	1/28/2016	2/4/2016	Hydromorphone	8 MG	04916	DE Medicaid	\$62.88
894122	TS	ZJ	1/25/2016	3/1/2016	Diazepam	10 MG	04916	DE Medicaid	\$1.53
901438	TS	DS-D	2/25/2016	3/5/2016	Fentanyl	50 MCG/HR	04916	DE Medicaid	\$90.17
902480	TS	DS	2/25/2016	3/5/2016	Hydromorphone	8 MG	04916	DE Medicaid	\$62.88
894122	TS	ZJ	1/25/2016	5/30/2016	Diazepam	10 MG	04916	DE Medicaid	\$2.53

³ Upon information and belief, the United States alleges that Prescriber DS-D and Prescriber DS are the same person. The United States also alleges, upon information and belief, that Prescribers DS-D, DH, and MA practiced at one address, and prescribers ZJ and SP practiced at a different address.

RX #	Patient	Prescriber	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
920547	TS	DS	5/26/2016	6/3/2016	Lyrica	150 MG	04916	DE Medicaid	\$354.52
920554	TS	DS-D	5/26/2016	6/3/2016	Fentanyl	50 MCG/HR	04916	DE Medicaid	\$90.17
920555	TS	DS-D	5/26/2016	6/3/2016	Oxycodone Hcl	15 MG	04916	DE Medicaid	\$43.33
894122	TS	ZJ	1/25/2016	6/30/2016	Diazepam	10 MG	04916	DE Medicaid	\$2.53
931528	TS	SP	7/26/2016	7/27/2016	Diazepam	10 MG	04916	DE Medicaid	\$3.03
951584	TS	DH	10/27/2016	10/27/2016	Fentanyl	50 MCG/HR	04916	DE Medicaid	\$173.35
955008	TS	SP	11/11/2016	11/11/2016	Diazepam	10 MG	04916	DE Medicaid	\$1.77
955008	TS	SP	11/11/2016	12/13/2016	Diazepam	10 MG	04916	DE Medicaid	\$1.72
984615	TS	DH	3/29/2017	4/3/2017	Fentanyl	50 MCG/HR	04916	DE Medicaid	\$166.54
983075	TS	SP	3/22/2017	4/19/2017	Diazepam	10 MG	04916	DE Medicaid	\$1.72
1497882	ST	JR	7/6/2015	7/6/2015	Oxycodone-Acetaminophen	5-325 MG	03741	Medicare	\$9.94
1503417	ST	WD	7/17/2015	7/17/2015	Oxycodone-Acetaminophen	5-325 MG	03741	Medicare	\$6.10
1504949	ST	JR	7/20/2015	7/22/2015	Oxycodone-Acetaminophen	5-325 MG	03741	Medicare	\$11.30
1510025	ST	WH	7/27/2015	8/3/2015	Oxycodone-Acetaminophen	5-325 MG	03741	Medicare	\$2.84

122. Each of the controlled substances listed in the chart is a prescription drug under the FDCA. These prescriptions were filled by Rite Aid Stores that had DEA registration numbers and NPI numbers in the name of the individual Rite Aid state entity (*i.e.*, Rite Aid of Delaware, Inc., Rite Aid of Virginia, Inc.). The reimbursements for these prescriptions were sent

into an account in the name of Rite Aid Hdqtrs., Corp. Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and, respectively, Rite Aid of Delaware, Inc., Rite Aid of Virginia, Inc. knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice. The claims for prescriptions listed as reimbursed by Federal Healthcare Programs were false because they were not valid prescriptions, were not for a medically accepted indication, and/or were not medically necessary.

5. Controlled Substance Prescriptions Issued by Prescribers Acting Outside the Usual Course of Professional Practice

123. Rite Aid Stores also dispensed unlawful prescriptions for controlled substances issued by prescribers who were acting outside the usual course of professional practice and who Rite Aid's pharmacists and Government Affairs Department knew were acting outside the scope of professional practice.

124. As alleged in more detail below in Sections IV.B.4 and IV.B.5 (§§ 155-204), Rite Aid pharmacists repeatedly warned Rite Aid's Government Affairs Department through tickets filed in Rite Aid's Retail Automated Customer Service (RACS) system about these prescribers, but the Government Affairs team failed to take action to prevent its stores from dispensing unlawful controlled substance prescriptions issued by these prescribers.

125. For example, Rite Aid Stores filled unlawful prescriptions issued by prescribers C.H., G.N., A.D., and William Bauer. The representative examples below include overlapping prescriptions for opioids, such as oxycodone and fentanyl, and prescriptions for opioids and combinations of controlled substances all written on the same day but filled at Rite Aid Stores for weeks or months thereafter. Several examples also show that Rite Aid Stores filled prescriptions for overlapping opioids for the same patient on the same day where one

prescription was reimbursed by a Federal Healthcare Program and the other was paid for with another form of payment.

a. Prescriber C.H. (Pennsylvania)

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
655634	AC	8/19/2014	8/19/2014	Oxycodone HCL	30 MG	01274	Medicare	\$8.80
655633	AC	8/19/2014	8/21/2014	Fentanyl	100 MCG/1 HR	01274	Medicare	\$8.80
655632	AC	8/19/2014	8/19/2014	Zolpidem Tartrate	5 MG	01274	Medicare	\$1.99
683013	GS	5/1/2015	5/4/2015	Oxycodone HCL	15 MG	01274	Medicare	\$22.50
682801	GS	5/1/2015	5/1/2015	Fentanyl	50 MCG/1 HR	01274	Medicare	\$36.05
683624	BS	5/7/2015	5/8/2015	Fentanyl	25 MCG/1 HR	01274	PA Medicaid	\$51.59

b. Prescriber G.N. (Pennsylvania)

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
1559436	SW	8/3/2015	8/4/2015	Oxycodone HCL	15 MG	01956	Medicare	\$33.05
1468612	EG	10/8/2014	10/9/2014	Oxycodone HCL	30 MG	01956	PA Medicaid	\$139.10
1468613	EG	10/8/2014	10/9/2014	Diazepam	5 MG	01956	PA Medicaid	\$2.46

c. Prescriber A.D. (Connecticut)

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
730806	MB	4/1/2015	5/6/2015	Fentanyl	25 MCG/1 HR	01790	Medicare	\$53.39
730804	MB	4/1/2015	5/6/2015	Fentanyl	100 MCG/1 HR	01790	Medicare	\$143.53
648295	BG	3/16/2015	3/24/2015	Oxycodone HCL	15 MG	02574	Medicare	\$5.70
650050	BG	3/16/2015	4/9/2015	Oxycontin ER	20 MG	02574	Medicare	\$83.40

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
651707	BG	3/16/2015	4/23/2015	Oxycodone HCL	15 MG	02574	Medicare	\$68.40
653019	BG	3/16/2015	5/7/2015	Oxycontin ER	40 MG	02574	Medicare	\$512.56
653018	BG	3/16/2015	5/7/2015	Oxycontin ER	20 MG	02574	Medicare	\$145.50
655241	BG	3/16/2015	5/26/2015	Oxycodone HCL	15 MG	02574	Medicare	\$56.25
656491	BG	3/16/2015	6/7/2015	Oxycontin ER	20 MG	02574	Medicare	\$145.50
656488	BG	3/16/2015	6/7/2015	Oxycontin ER	40 MG	02574	Medicare	\$512.56
658671	BG	3/16/2015	7/5/2015	Oxycontin ER	40 MG	02574	Medicare	\$512.56
660007	BG	3/16/2015	8/31/2015	Diazepam	5 MG	02574	Medicare	\$2.02
660007	BG	3/16/2015	7/14/2015	Diazepam	5 MG	02574	Medicare	\$2.08
772603	RA	5/23/2016	6/1/2016	Diazepam	10 MG	01790	Medicare	\$1.14
772604	RA	5/23/2016	6/1/2016	Morphine Sulfate ER	60 MG	01790	Medicare	\$26.08
772605	RA	5/23/2016	6/1/2016	Oxycodone HCL	10 MG	01790	Medicare	\$4.78
684317	JK	2/22/2016	2/22/2016	Oxycodone HCL ER	80 MG	02574	N/A	N/A
684316	JK	2/22/2016	2/22/2016	Oxycodone HCL	30 MG	02574	N/A	N/A
701776	JK	8/11/2016	9/10/2016	Oxycodone HCL	30 MG	02574	N/A	N/A
701777	JK	8/11/2016	9/10/2016	Oxycontin ER	80 MG	02574	Medicare	\$1,532.93
701785	JK	8/11/2016	9/13/2016	Diazepam	5 MG	02574	N/A	N/A

d. Prescriber William Bauer (Ohio)

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
842459	JM	2/6/2017	4/10/2017	Oxycodone HCL	10 MG	03179	Medicare	\$37.07
842452	JM	2/6/2017	2/6/2017	Oxycodone HCL	10 MG	03179	Medicare	\$37.07
842461	JM	2/6/2017	3/11/2017	Oxycontin ER	30 MG	03179	Medicare	\$15.76
842458	JM	2/6/2017	3/11/2017	Oxycodone HCL	10 MG	03179	Medicare	\$37.07
842462	JM	2/6/2017	4/10/2017	Oxycontin ER	30 MG	03179	Medicare	\$15.76
842460	JM	2/6/2017	5/14/2017	Oxycodone HCL	10 MG	03179	Medicare	\$37.07
842463	JM	2/6/2017	5/14/2017	Oxycontin ER	30 MG	03179	Medicare	\$15.76
842464	JM	2/6/2017	6/27/2017	Lyrica	100 MG	03179	Medicare	\$17.10
842464	JM	2/6/2017	5/2/2017	Lyrica	100 MG	03179	Medicare	\$16.36

RX #	Patient	RX Written Date	RX Dispense Date	Drug Name	Drug Strength	Store #	Govt Payor	Govt Paid Amt
817266	MC	2/2/2017	2/2/2017	Oxycodone HCL	30 MG	03357	Ohio Medicaid	\$34.51
817268	MC	2/2/2017	2/2/2017	Oxycodone HCL	30 MG	03357	Ohio Medicaid	\$34.51
821606	MC	2/2/2017	3/4/2017	Oxycodone HCL	30 MG	03357	Ohio Medicaid	\$42.96
824512	MC	3/23/2017	3/24/2017	Methadone HCL	10 MG	03357	N/A	N/A
824511	MC	3/23/2017	3/24/2017	Oxycodone HCL	30 MG	03357	N/A	N/A
826713	MC	4/10/2017	4/11/2017	Methadone HCL	10 MG	03357	N/A	N/A
829688	MC	5/1/2017	5/1/2017	Methadone HCL	10 MG	03357	N/A	N/A
829686	MC	5/1/2017	5/1/2017	Oxycodone HCL	30 MG	03357	N/A	N/A
833954	MC	5/31/2017	5/31/2017	Oxycodone HCL	30 MG	03357	Ohio Medicaid	\$20.90
834798	MC	5/31/2017	6/7/2017	Methadone HCL	10 MG	03357	N/A	N/A
843175	MC	6/29/2017	8/9/2017	Methadone HCL	10 MG	03357	N/A	N/A
847019	MC	6/29/2017	9/6/2017	Methadone HCL	10 MG	03357	N/A	N/A
928113	MB	7/13/2018	10/4/2018	Oxycodone HCL	30 MG	03179	N/A	N/A
923606	MB	7/13/2018	9/4/2018	Oxycodone HCL	30 MG	03179	N/A	N/A
919444	MB	7/13/2018	8/5/2018	Oxycodone HCL	30 MG	03179	N/A	N/A
928112	MB	7/13/2018	10/4/2018	Hydrocodone-Acetaminophen	5 MG-325 MG	03179	Ohio Medicaid	\$10.18
923608	MB	7/13/2018	9/4/2018	Hydrocodone-Acetaminophen	5 MG-325 MG	03179	Ohio Medicaid	\$10.18
919216	MB	7/13/2018	8/5/2018	Hydrocodone-Acetaminophen	5 MG-325 MG	03179	Ohio Medicaid	\$10.18

126. Each of the controlled substances listed in the charts is a prescription drug under the FDCA. These prescriptions were filled by Rite Aid Stores that had DEA registration numbers and NPI numbers in the name of the individual Rite Aid state entity (*i.e.*, Rite Aid of

Pennsylvania, Inc., Rite Aid of Connecticut, Inc., and Rite Aid of Ohio, Inc.). The reimbursements for these prescriptions were sent into an account in the name of Rite Aid Hdqtrs., Corp. Defendants Rite Aid Hdqtrs., Corp., Rite Aid Corporation, and, respectively, Rite Aid of Pennsylvania, Inc., Rite Aid of Connecticut, Inc., and Rite Aid of Ohio, Inc. knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice. The claims for prescriptions listed above as reimbursed by Federal Healthcare Programs also were false because they were not valid prescriptions, were not for a medically accepted indication, and/or were not medically necessary.

B. RITE AID KNEW IT WAS DISPENSING UNLAWFUL CONTROLLED SUBSTANCES

127. It has been long recognized in the pharmacy profession that pharmacists must identify and assess red flags to determine whether a prescription is valid. This professional obligation is consistent with pharmacists' long-standing "corresponding responsibility," under 21 C.F.R. § 1306.04(a), to determine whether a prescription was issued for a legitimate medical purpose and in the usual course of professional practice.

128. Rite Aid Corporation acknowledged that "[f]ederal regulations impose a 'corresponding responsibility' on pharmacies and pharmacists" and "vests Rite Aid with discretionary authority to determine whether to fill prescriptions for controlled substances." Brief for Respondent Rite Aid Corp., *Stuart Hartman, D.O. v. Rite Aid Corp., et al.*, No. 2016-00768 (June 7, 2016). Rite Aid's Director of Government Affairs, Janet G. Hart, filed an accompanying declaration in that action, in which she emphasized that 21 C.F.R. § 1306.04 outlines "'corresponding responsibilities' of pharmacies and pharmacists to ensure that prescriptions are issued for legitimate medical purposes and to ensure that prescriptions are not

for purposes of abuse.” As recently as February 12, 2019, Senior Vice President (SVP) for Regulatory Affairs Daniel Miller, to whom Hart reported, emailed all Rite Aid pharmacists regarding their corresponding responsibility and stated, “[t]he consequences of failing to perform adequate due diligence can have significant civil, criminal, and financial impact for the individual pharmacist and Rite Aid.”

129. To meet their legal obligation of “corresponding responsibility,” pharmacies have tools available in real time for its pharmacists, relying on their training and experience, to make an assessment about the medical necessity and validity of a prescription, such as: (1) observing the patient when she presents the prescription at the pharmacy; (2) calling the prescriber to confirm the medical necessity of the prescription; and (3) consulting the state-run Prescription Drug Monitoring Program (PDMP) databases that contain information on each dispensing event, such as the drug dispensed, date dispensed, patient identifier, pharmacy identifier, and prescriber identifier. State laws in fact require such due diligence on the part of the pharmacy.

130. Despite its awareness of its obligations to comply with federal rules and regulations and to exercise its corresponding responsibility in dispensing controlled substances, Rite Aid knowingly, at least with willful blindness, filled unlawful prescriptions for controlled substances, as set forth above in Section IV.A. Rite Aid knew that these prescriptions were unlawful because Rite Aid pharmacists repeatedly dispensed controlled substances that had clear red flags that were highly indicative that the prescriptions were unlawful. By filling these prescriptions, Rite Aid’s pharmacists ignored their training and Rite Aid’s own flawed controlled substance dispensing protocol that purported to require pharmacists to identify and resolve red flags. Aware that its pharmacists repeatedly violated Rite Aid’s dispensing protocol, Rite Aid knew, through its Government Affairs Department, that pharmacists routinely and pervasively

filled unlawful prescriptions. Rite Aid also knew this from information provided by certain pharmacists, its own internal data, and its distributor, McKesson Corporation. Rather than taking action to prevent such unlawful dispensing, however, Rite Aid's Government Affairs Department repeatedly directed analysts in Rite Aid's Third Party Industry Relations Department to delete notes about suspicious prescribers that Rite Aid pharmacists added to prescriber profiles. This further exacerbated and continued the filling of unlawful prescriptions written by those prescribers because it made it more difficult for Rite Aid pharmacists to share important information with each other about problematic prescribers.

131. As a result, Defendants had knowledge, within the meaning of the CSA and FCA, that they were dispensing unlawful prescriptions for controlled substances and, where the customer had government insurance, submitting false claims to Federal Healthcare Programs.

1. Rite Aid Pharmacists Filled Unlawful Controlled Substance Prescriptions Knowingly

132. As alleged above in Section IV.A., Rite Aid pharmacists filled at least hundreds of thousands of unlawful prescriptions for controlled substances with clear red flags, which highly indicated that the prescriptions were unlawful. As a result, Rite Aid pharmacists filled such prescriptions with actual knowledge, or at least with willful blindness, that the prescriptions were unlawful.

133. These unlawful prescriptions had clear red flags, often multiple ones, which indicated misuse related to the prescription itself, the prescriber, the customer, or a combination of all of these and other factors.

134. Rite Aid pharmacists were trained to recognize and assess red flags and to determine whether a prescription is valid and should be filled. Schools of pharmacy, for example, generally include courses covering red flags in their standard curricula. Pharmacists

are trained that a prescription may be invalid even if it is signed by a prescriber. Pharmacists also have professional experience in assessing whether a prescription with one or more red flags is unlawful.

135. Despite the obvious nature of many of the red flags they encountered, and their professional experience and training that such red flags needed to be resolved before filling a prescription, Rite Aid pharmacists filled such prescriptions without any effort, or an inadequate effort, to resolve these clear red flags.

136. Hard copy prescriptions with red flags, for example, sometimes lacked any notation from Rite Aid pharmacist to suggest that he or she had made any effort to resolve red flags before filling these prescriptions. Those that did have some notation stated that the pharmacists had made an inquiry without any indication that the pharmacist resolved the red flags, if even possible to do so.

137. By filling unlawful prescriptions for controlled substances without resolving clear red flags as to the prescriptions' unlawfulness, Rite Aid pharmacists did so with actual knowledge, or at least willful blindness.

2. Rite Aid Knew That Its Dispensing Protocol Was Highly Flawed and Did Not Prevent Unlawful Dispensing

138. Recognizing that certain controlled substances were considered to be more susceptible to diversion and that it was necessary to confirm the validity of such prescriptions before filling them, Rite Aid created a dispensing protocol called the "High Alert Review Process" purportedly designed to identify "potential dispensing/prescribing abnormalities" before pharmacists dispensed those controlled substances. But it was little more than lip service. The protocol was highly flawed, routinely ignored, and missed critical, highly diverted controlled substances.

139. The “High Alert Review Process” was supposed to be applied to the dispensing of the following controlled substances: (1) all strengths of oxycodone products; (2) methadone ten (10) milligrams; (3) hydrocodone ten (10) milligrams/acetaminophen three-hundred-and-twenty-five (325) milligrams, which is a combination prescription drug containing both hydrocodone and acetaminophen; (4) fentanyl products; and (5) all controlled substance prescriptions paid in cash or with a discount card for more than \$1,000.

140. For these controlled substances, Rite Aid pharmacists were supposed to undertake a six-step process, known as “High Alert Controlled Substance Validation.” The six steps were: (1) review prescription; (2) validate prescription; (3) validate prescriber; (4) validate patient; (5) dispense or not; and (6) report suspicious activity.

141. Before filling prescriptions for these controlled substances, Rite Aid pharmacists were supposed to look for certain specific red flags because Rite Aid knew that they were strong indicators of unlawful prescribing. These included high quantities, trinity combinations, and patient/prescriber outside the pharmacist’s normal geography. The protocol also identified the following additional red flags as ones that pharmacists were supposed to look for in “validating a prescriber” because Rite Aid knew they also were strong indicators of unlawful prescribing:

- a. “Prescriber writes for the same or similar medications in the same strength and quantity for many or multiple patients particularly without regard to the patient’s age, sex, height, weight, other existing medical conditions;
- b. Prescriber writes for the same ‘cocktail’ or combination of drugs (Opioid + Muscle Relaxant + Benzodiazepine);
- c. Prescriber writes for excessive quantities;
- d. Prescriber is located outside the pharmacy’s typical geographical area;

- e. Prescriber writes a prescription outside their normal scope of practice[;]
- f. Well known that the prescriber does not take insurance; and
- g. Patients from a particular prescriber come in groups.”

142. Early fills were also added to the protocol as a red flag because Rite Aid knew they were an indicator of “over-utilization of medications.” In June 2016, Rite Aid updated its dispensing software, NexGen, to alert pharmacy associates in red text when a prescription for a controlled substance was early. Nonetheless, a Rite Aid pharmacist could override the system and dispense the medication early, but pharmacists were instructed to always document a reason for doing so in the NexGen system or on the paper prescription.

143. Rite Aid’s protocol was nothing more than a fig leaf.

144. First, it did not cover commonly diverted controlled substances. For example, a presentation created by a Rite Aid pharmacist and district manager that was intended for the National Association of Drug Diversion Investigators and sent to Government Affairs Director Janet Hart and SVP Daniel Miller in December 2016 listed a number of “[m]ost [c]ommonly [d]iverted” opioids that were excluded from the dispensing protocol, including codeine and morphine; central nervous system depressants, including benzodiazepines and muscle relaxants; and stimulants, including amphetamine combination products.

145. Second, Rite Aid knew that its High Alert Review Process did not prevent pharmacists from filling unlawful prescriptions because, for example, the dispensing system would “auto fail” and prevent the pharmacist from restarting the prescription in the dispensing software only where a pharmacist answered “no” to two questions: (1) is the prescription validated under Rite Aid’s protocol; and (2) is there a valid patient-prescriber relationship. For any other question, if the pharmacist answered “no,” Rite Aid pharmacists could complete the

process and fill the prescription by typing comments into the notes field. Rite Aid pharmacists could type any explanation in that field to work around this validation process.

146. As a result, Rite Aid's dispensing protocol proved to be little more than lip service to its corresponding responsibility, and Rite Aid knew that its pharmacists routinely dispensed unlawful controlled substances containing the very red flags that Rite Aid knew were indicative of unlawful prescribing and that the protocol indicated should not be filled.

3. Rite Aid's Regulatory Affairs Department Knew That Pharmacists At Its Stores Were Repeatedly Filling Unlawful Prescriptions

147. Rite Aid, through analysts in its department known as Regulatory Affairs (which, after October 2015, also included the department known as Government Affairs), knew that Rite Aid pharmacists were routinely filling unlawful prescriptions.

148. Rite Aid's Regulatory Affairs Department monitored dispensing data for prescriptions that fell into more specific "high alert" categories, such as (1) prescriptions dispensed in excess of five hundred (500) tablets or more, unless the controlled substance was hydrocodone, in which case it was flagged at two-hundred-and-forty (240) tablets; (2) prescriptions paid with cash or a discount card; and (3) prescriptions costing more than \$1,000.

149. Using this more specific criteria, analysts in Rite Aid's Regulatory Affairs Department purportedly reviewed the prescriptions in the "high alert" categories after they had been dispensed for the following occurrences:

- a. Early prescription fills;
- b. Multiple prescribers dispensing the same controlled substance to the same patient;
- c. A patient filling prescriptions at multiple store locations;
- d. Excessive or irregular prescription patterns;

- e. Prescriptions that were previously flagged;
- f. Patients that only have prescriptions for controlled substances; and
- g. Patients with morphine milligram equivalents in excess of the CDC benchmark of ninety (90) morphine milligram equivalent (MME⁴) for a dangerous dose.

150. Upon identifying a prescription meeting one or more of the requirements above, an analyst in Rite Aid's Regulatory Affairs Department could send a "High Alert Follow Up Request" to the District Leader overseeing the dispensing pharmacy to review the circumstances surrounding the dispensing of the prescription. The District Leader would then report back to Regulatory Affairs about that prescription and his or her findings.

151. Through the review of these Follow Up Request forms, analysts in Rite Aid's Regulatory Affairs Department often learned that stores had not followed Rite Aid's dispensing protocol. However, other than the District Leader reviewing that prescription with the pharmacist who filled it, the Regulatory Affairs Department took no broader action to curb unlawful dispensing at Rite Aid Stores.

152. For example, after flagging a prescription as an early fill using a discount savings card, a Rite Aid Regulatory Affairs Senior Analyst sent a High Alert Reporting Follow Up form to Store 03637 in Pennsylvania, copied Janet Hart, and received a response in which the pharmacy district manager indicated the store pharmacist: (1) had not followed Rite Aid's validation steps in the dispensing protocol, which would have identified the prescription as an early fill; (2) had not checked the PDMP data, which would have indicated the existence of other red flags, including fills at other non-Rite Aid pharmacies; and (3) had ignored other controlled substance prescriptions of concern on the patient's profile.

⁴ MME are values that represent the potency of an opioid dose relative to morphine.

153. Similarly, Rite Aid's Regulatory Affairs Department received a High Alert Reporting Follow Up form for Store 10289 in New Hampshire in which the pharmacy district manager reported that the store pharmacist had filled a methadone prescription early using a discount savings card for a patient for whom Rite Aid had previously dispensed medication, but without any record evidencing that the pharmacist had: (1) recognized and resolved the red flags; and (2) followed Rite Aid's dispensing protocol.

154. Despite receiving information in these and other circumstances that its Stores failed to follow Rite Aid's dispensing protocol, Rite Aid took no action to curb the dispensing of unlawful controlled substances at those Stores.

4. When Rite Aid's Own Pharmacists Made Members of Rite Aid's Government Affairs Department Aware Of Suspicious Prescribers And Prescriptions, Rite Aid Failed To Act At The Corporate Level

155. The final step of Rite Aid's six-step High Alert Controlled Substance Validation system for validating high-alert controlled substances required Rite Aid pharmacists to "report suspicious activity." Rite Aid told its pharmacists that they had a duty to report "suspicious activity" and that they could do so by submitting a ticket through an internal reporting system, currently through a system called ServiceNow and formerly through RACS (throughout this Complaint, reports regarding prescribers to both ServiceNow and RACS are referred to uniformly as "tickets"). Pharmacists and other Rite Aid employees also would report in RACS non-dispensing related complaints or issues, such as problems with software, insurance, printers, and other hardware.

156. Rite Aid's Government Affairs Department—responsible for, among other things, ensuring corporate compliance with federal and state regulations—received and reviewed these tickets and the suspicious prescribers identified by its pharmacists.

157. Despite having the RACS system, Rite Aid: (1) failed to train pharmacists on how to use it; and (2) even when its pharmacists did submit tickets, Rite Aid's Government Affairs Department often ignored them.

158. Rite Aid knew that certain behaviors were highly suspicious and suggestive of unlawful prescribing. For example, in March 2013, Rite Aid told its pharmacists to report such conduct and to submit tickets to Rite Aid's Government Affairs Department if they had concerns about "prescribing patterns, prescribers from areas significantly outside the pharmacy's typical geographic area, or if other pharmacies are refusing to fill prescriptions from a particular prescriber or prescriber group."

159. In February 2015, Rite Aid provided the following additional examples of suspicious activity that warranted close scrutiny, further inquiry, and a RACS ticket:

- a. "High frequency/quantity of controlled substance prescriptions[;]
- b. Trinity prescribing[;]
- c. Patients or prescriber out of your geographic area."

160. Yet, even as Rite Aid knew certain conduct was highly suspicious, and ostensibly had a system to detect unlawful prescribing, Rite Aid failed to adequately train its pharmacists to report suspicious prescribing through Rite Aid's reporting system, which depended on pharmacists filing tickets in the first instance to be effective. Many Rite Aid pharmacists were not even aware of a system for reporting suspicious prescribers. Other pharmacists became aware of it only after discovering it on their own but received no formal training on how to use it.

161. Even so, many Rite Aid pharmacists submitted tickets reporting suspicious prescribers and prescriptions presented at Rite Aid Stores. Rite Aid assigned only one Government Affairs employee to review all of the tickets submitted to Rite Aid by pharmacists

nationwide. From February 2013 through February 2018, that employee was a pharmacy technician. After that employee separated from Rite Aid in February 2018, at which time there were *thousands* of tickets pending, the initial reviews were conducted either by a different pharmacy technician or the technician's supervisor, Janet Hart.

162. Through its review of these tickets, Rite Aid knew that its stores were receiving prescriptions that had the same red flags it incorporated into its dispensing guidelines, including, for example, prescriptions for the trinity cocktail, prescriptions for dangerous combinations of controlled substances, prescriptions for excessively high doses of controlled substances, and prescriptions from prescribers who prescribed the same controlled substance(s) to patients.

163. Nonetheless, many of these tickets were simply closed immediately, without any further action by Rite Aid to stop filling unlawful prescriptions.

164. When a Rite Aid Government Affairs employee responded to the ticket, the employee often provided the pharmacist with only a generic instruction to continue using "sound professional judgment" and to follow Rite Aid's six-step High Alert Controlled Substance Validation protocol.

165. For example, an Ohio pharmacist submitted a RACS ticket questioning suboxone prescriptions written by Prescriber J.H., in Ohio, whose practice operated as a sports medicine clinic. Suboxone, which can be abused, is approved solely to treat opioid use disorder, and is not typically prescribed by sports medicine clinics. A Rite Aid Government Affairs employee responded to this pharmacist's RACS ticket by email to say that the "only purpose" of RACS is to "identify trends in prescribing habits that may indicate a prescriber is making a significant contribution to the abuse and diversion of controlled substances that puts the DEA Registrations of our stores and McKesson's warehouses at risk." The Rite Aid employee went on to say that

the pharmacist is responsible for following the High Alert Review Process, reviewing red flags, and exercising sound judgment, but that Rite Aid does “not advise on isolated situations, investigate fraudulent prescriptions or stolen prescription pads and do[es] not have access to edit prescriber files in NexGen.” This Rite Aid employee copied not only the pharmacist who submitted the ticket, but also her regional supervisors, including a District Manager, and a Regional Vice President of Pharmacy Operations.

166. A pharmacy manager in Pennsylvania received similarly generic responses to tickets but continued to submit tickets on up to eleven different prescribers. For example, on or around May 1, 2014, the pharmacy manager submitted a RACS ticket on seven Philadelphia prescribers related to their prescriptions, which were exclusively for suboxone and clonazepam and which patients traveled to Bristol, Pennsylvania (twenty-seven miles away) to fill.

167. More generally, this pharmacy manager reported that the District Manager and the regional Vice President overseeing the store stated that the pharmacy manager was required to fill all prescriptions unless Rite Aid performed a corporate block on the prescriber, which Rite Aid rarely did. Finally, the pharmacy manager was told that the only instance in which a prescription could be rejected was if the customer traveled a far distance to fill the prescription.

168. Another Pennsylvania pharmacist submitted a ticket on Prescriber J.R. because the prescriber could not be reached by phone to verify narcotic prescriptions, patients paid cash for their prescriptions, and the handwriting on J.R.’s prescriptions varied greatly, which can indicate the prescription has been forged. In response, a Rite Aid Government Affairs analyst said that the company was aware of J.R.’s activities but provided no guidance to the pharmacist.

169. The same Pennsylvania pharmacist received no response from Rite Aid’s Government Affairs Department to another ticket reporting Prescriber D.E. and two other

prescribers for issuing similar prescriptions for high volumes of oxycodone and methadone. The pharmacist believed that Rite Aid ignored her complaints, so the pharmacist stopped submitting tickets.

170. Yet another pharmacist who submitted a ticket on Prescriber V.O., in Maryland, received an initial response from Rite Aid's Government Affairs analyst that it was the obligation of the pharmacist, not Rite Aid corporate, to ensure the prescription was legitimate and that prior reviews of dispensing data did not support action from the corporate level.

171. After reviewing V.O.'s data the following day, which showed that V.O. had not only prescribed trinity medications to numerous patients and similar controlled substances to family members, but also that he had recently been reprimanded and prohibited from practicing pain management by a state authority, Rite Aid's Government Affairs analyst replied to the ticket to say that the data did not show a "definite pattern of suspicious prescribing habits however, it does seem to be trending in that direction."

172. Just as frequently, the Rite Aid Government Affairs analyst tasked with responding to tickets simply told reporting pharmacists to rely on their own "sound professional judgment."

173. For example, an Ohio pharmacist submitted a ticket on Prescriber R.C. regarding multiple prescriptions for Norco, a combination medication including both hydrocodone and acetaminophen, and a patient who had been prescribed Norco and Percocet, both immediate release opioids, at the same time. A Rite Aid Government Affairs analyst responded that it had reviewed Prescriber R.C.'s prescriptions and did not see sufficient evidence to warrant corporate action and further directed the pharmacist to use "professional judgement" when dispensing prescriptions issued by R.C.

174. The pharmacist was taken aback by this response and received no other feedback, follow-up, or guidance from Rite Aid corporate as to the dispensing protocol for prescriptions issued by R.C.

175. In contrast to the generic instruction that Rite Aid Government Affairs analysts repeatedly gave to Rite Aid pharmacists to exercise their own professional judgment, Rite Aid Corporation took a different course when a customer complained that a prescription was not filled. For example, two Rite Aid pharmacists at Pennsylvania locations reported that if customers complained to Rite Aid corporate about a pharmacist's refusal to fill a prescription, the corporate office would follow up with the pharmacist to question why the prescription was not filled. If Rite Aid did not find the pharmacist's explanation to be sufficient, then Rite Aid would direct the pharmacist to fill the prescription.

176. As a result of Rite Aid Corporation's actions, Rite Aid pharmacists were dissuaded from filing additional tickets, and Rite Aid Stores continued to fill prescriptions from prescribers that Rite Aid's pharmacy employees had identified as suspicious and problematic.

5. Rite Aid's Reviews of Suspicious Prescribers and Prescriptions, When Such a Review Even Occurred, Lacked Fixed Criteria For Decision-Making and Often Languished With Rite Aid Taking No Action

177. Although the vast majority of tickets were subjected to little or no scrutiny, Rite Aid's Government Affairs Department, at times, further investigated prescribers identified in tickets. Government Affairs, however, frequently allowed those reviews to languish, which, in an overwhelming number of cases, resulted in Rite Aid doing nothing to curb on-going, unlawful filling of prescriptions issued by those prescribers at Rite Aid Stores.

178. Where Rite Aid's Government Affairs analysts did look more closely at prescribers identified mostly by its pharmacists, they reviewed information that would bear on whether the prescriber's controlled substance prescriptions should be filled. These included:

(1) Rite Aid's dispensing data for the prescriber; (2) information about the prescriber, including whether the prescriber had a valid DEA registration number and any history of disciplinary action; (3) internet research on the prescriber and the prescriber's office; and (4) in and after December 2013, dispensing data that Rite Aid purchased from a commercial entity comprising approximately ninety percent of all retail pharmacies in the country.

179. The Government Affairs analyst performed this review and had sole discretion whether to elevate the file for further review by Janet Hart. Hart could unilaterally end the review, direct the analyst to re-run the dispensing data in six months, or present the file to a three-person committee of Rite Aid employees (the Review Committee), including Hart, to determine what, if any, course of action to take on that prescriber.

180. Rite Aid's Review Committee rarely met and even more rarely instituted corporate blocks that prohibited its Stores from filling prescriptions for controlled substances from a prescriber. Rite Aid instituted prescriber blocks in only a small fraction of cases (less than four percent of the over 3,300 prescribers with a review file, as of 2015, and less than three percent of over 4,600 prescriber files, as of 2017).

181. More often than not, in the face of overwhelming evidence demonstrating unlawful prescriptions that it knew its pharmacists had and would continue to fill, Rite Aid Corporation did nothing, and its Stores continued filling unlawful prescriptions from prescribers identified as suspicious by its own pharmacists.

a. Prescriber C.H. (Pennsylvania)

182. By way of example, as early as 2015, Rite Aid pharmacists repeatedly warned Rite Aid's Government Affairs Department about prescriptions written by Prescriber C.H., a Pennsylvania physician specializing in Internal Medicine. Both prior to and after receiving tickets about C.H., a Rite Aid Government Affairs analyst reviewed C.H.'s prescribing habits,

doing so five times between September 2014 and October 2016. Throughout this time period, Rite Aid continued to fill unlawful prescriptions written by C.H.

183. For example, in September 2014, Rite Aid's Government Affairs Department reviewed for at least the second time the prescribing habits of C.H. and his prescription fills at Rite Aid Stores, identifying multiple patients who had received prescriptions of trinity medications and families of patients who were prescribed the same or similar controlled substances. Rite Aid performed another such prescriber review in December 2014 and again identified trinity prescriptions and family members who received the same or similar controlled substances.

184. Despite receiving tickets and conducting reviews of C.H.'s prescribing habits, the Review Committee closed its file on C.H. in February 2015 without written explanation by affixing a sticky note to the hard copy file that said "Close, No Action."

185. Rite Aid pharmacists continued to complain, however, about prescriptions presented at their stores by C.H.'s patients. For example, in May 2015, shortly after Rite Aid closed its file, a Rite Aid pharmacist complained that C.H. prescribed fentanyl patches for patients where such patches "are not recommended" and prescribed daily dosages of oxycodone that "exceeded manufacturer limitations." Rite Aid's Government Affairs analyst responded the next day that there was not "sufficient data to support action from the corporate level."

186. One month later, in June 2015, a Rite Aid pharmacist in Delaware complained to Rite Aid that the pharmacy had received prescriptions from C.H. for "oxycodone 15mg, large quantities," despite C.H. practicing in Pennsylvania.

187. A few months later, in September 2015, yet another Rite Aid pharmacist submitted a ticket about C.H., complaining to Rite Aid's Government Affairs Department that

there was “more and more suspicious activity from this doctor,” including patients with insurance seeking to pay cash for prescriptions to avoid auto-rejection for early fills.

188. Approximately two weeks later, also in September 2015, a separate Rite Aid pharmacist complained to Rite Aid that C.H. tended to prescribe patients multiple prescriptions for oxycodone of different strengths simultaneously.

189. Rite Aid’s Government Affairs Department continued to review C.H.’s prescribing habits after receiving these pharmacist tickets. As with the earlier reviews, Rite Aid’s Government Affairs analyst performed a review in June 2015 and identified patients receiving prescriptions for trinity medications and family members receiving prescriptions for the same or similar controlled substances. Two more reviews with similar findings occurred in 2016. Each time, Rite Aid continued to fill prescriptions from C.H. and, where applicable, seek reimbursement from Federal Healthcare Programs for patients with government health insurance.

190. Examples of Rite Aid’s continued filling of unlawful prescriptions issued by C.H. are set forth above in Paragraph 125.a, including prescriptions for fentanyl or both oxycodone and fentanyl.

b. Prescriber G.N. (Pennsylvania)

191. At least as early as April 2015, Rite Aid pharmacists repeatedly warned Rite Aid’s Government Affairs Department about the prescribing habits of Prescriber G.N. in Philadelphia, Pennsylvania. Rite Aid’s Government Affairs Department received at least four tickets about G.N. and completed at least two reviews of G.N.’s prescribing habits. Nevertheless, Rite Aid continued to fill unlawful prescriptions written by G.N.

192. One Rite Aid pharmacist warned Rite Aid in a ticket submitted in April 2015 that G.N. prescribed zolpidem, alprazolam, cyclobenzaprine, oxycodone 30 milligrams, and hydrocodone 7.5/325 milligrams, to the same patient in the same visit. This is a dangerous

combination of drugs that includes not only all three prescription drugs in the commonly diverted trinity combination but also a sedative.

193. The pharmacist also warned that G.N. admitted by phone that G.N. instructed patients to take their oxycodone prescriptions and hydrocodone prescriptions to different pharmacies to get them filled, prompting that pharmacist to no longer fill G.N.'s prescriptions.

194. Shortly thereafter, another Rite Aid pharmacist warned Rite Aid in a ticket that G.N. prescribed the same unnecessary opioids to patients, writing that G.N.'s prescriptions were for the "same drug cocktails for all patients," who "do not seem to be in overt pain and many are able-bodied young men. MD office is known well to be a pill mill. Please look into this MD." Nonetheless, Rite Aid's Government Affairs analyst responded less than an hour later that corporate had already reviewed G.N. and the data "did not seem to indicate a significant contribution to the abuse and diversion of controlled substances that warrants action from the corporate level."

195. That internal data, however, actually revealed that: (1) almost thirty percent of G.N.'s prescriptions filled by Rite Aid Stores were for schedule II controlled substances; (2) G.N. prescribed trinity medications to at least five patients in the past six months; and (3) G.N. prescribed similar controlled substances to family members.

196. The following year in December 2016 and after receiving another ticket, Rite Aid's Government Affairs team requested that another staff member delete "unacceptable" comments added by pharmacy staff about G.N. in Rite Aid's dispensing software, including "HIS PT'S FILLS SAME...", "DO NOT FILL," and "FAKE CONTROLS."

197. Yet, throughout this time and with the benefit of this data, Rite Aid continued to fill prescriptions for controlled substances, including oxycodone and opioid combinations, from

G.N. and, where applicable, submit reimbursement claims to Federal Healthcare Programs for patients with government health insurance, as alleged above in Paragraph 125.b.

c. Prescriber A.D. (Connecticut)

198. Beginning as early as February 2015, Rite Aid pharmacists warned Rite Aid's Government Affairs Department about the prescribing habits of A.D., an advanced practice registered nurse in Connecticut. For example, a pharmacist questioned the legitimacy and necessity of her prescriptions providing an example of a patient who had a prescription for high dosages of fentanyl tablets for a sore ankle, but who walked away quickly with no pain. The pharmacists warned that this was a "[v]ery suspicious practice that prescribes quantities above normal protocols."

199. From February 2015 through September 2016 alone, Rite Aid's Government Affairs Department analyzed A.D.'s prescribing habits four times, the first of which revealed that seventy-six percent of prescriptions filled by Rite Aid Stores were for schedule II controlled substances. All of those internal reviews showed that A.D. prescribed trinity medications to patients and, often, similar controlled substances to family members. Throughout this time, Rite Aid Stores continued to fill A.D.'s prescriptions and, where applicable, seek reimbursement from Federal Healthcare Programs.

200. Indeed, Rite Aid knowingly dispensed controlled substances pursuant to unlawful prescriptions written by A.D., examples of which are set forth above in Paragraph 125.c, including prescriptions for fentanyl and for oxycodone in multiple strengths simultaneously and, at times, in combination with other opioids and multiple prescriptions for controlled substances issued on the same day, which patients presented at a Rite Aid Store for several weeks or months thereafter.

d. Prescriber William Bauer (Ohio)

201. As early as 2015, Rite Aid pharmacists warned Rite Aid's Government Affairs Department in tickets about the prescribing habits of William Bauer, a neurologist in Ohio. These pharmacists repeatedly questioned the legitimacy and necessity of the prescriptions presented at their stores by Bauer's patients, and yet Rite Aid continued to fill his prescriptions until April 2019, shortly before a federal indictment in August 2019.

202. For example, in May 2018 a pharmacist warned Rite Aid Government Affairs that Bauer "writes a lot of control medications for patients, with several patients on multiple pain meds."

203. In September 2018, another pharmacist warned that Bauer's practice had been "prescribing large quantity of opioids with similar diagnosis codes" and that "the number of patients that are on opioids for this diagnosis and the quantity being prescribed make me believe this office is relying too much on opioids for treatment." Janet Hart responded to that ticket that she would review the prescriber, but that she was "[c]losing the ticket." Rite Aid continued filling Bauer's prescriptions until April 2019.

204. Prior to and even after these tickets, Rite Aid knowingly filled prescriptions written by Bauer and submitted reimbursement claims to Federal Healthcare Programs for oxycodone, hydrocodone, and other controlled substances, examples of which are set forth above in Paragraph 125.d, including prescriptions for overlapping opioids and prescriptions that Bauer issued on the same day to patients, but that patients filled over the course of many weeks or months at Rite Aid Stores.

6. Rite Aid Deleted Notes About Suspicious Prescribers in Prescriber Profiles That Were Drafted by Pharmacists and Store Employees, Preventing Them From Sharing Their Concerns

205. Not only did Rite Aid's Government Affairs Department fail to respond to tickets sent by its pharmacists to corporate headquarters, it sought to cover up Rite Aid's unlawful conduct. Rite Aid's Government Affairs Department did so by repeatedly directing employees in another Rite Aid department to delete notes that Rite Aid pharmacists added to internal prescriber profiles in NexGen, Rite Aid's dispensing system. This showed that Rite Aid and its pharmacists knew it had and would continue to dispense unlawful prescriptions. This practice also limited what its pharmacists could share with other Rite Aid pharmacists about suspicious prescribers.

206. Only a group within Rite Aid known as Third Party Industry Relations was authorized to delete information from a prescriber profile. When a Rite Aid Government Affairs analyst found a note in the prescriber profile like those alleged below, the analyst would send an email to a Third Party Industry Relations employee and direct him or her to remove the note(s) from the prescriber profile.

207. For example, on March 19, 2015, a Rite Aid Government Affairs analyst admonished a Rite Aid pharmacist via email for a note that the pharmacist had added to a profile for a prescriber with the initials M.L. The Government Affairs analyst stated that the note would be removed and that the pharmacist should "remember to always be very cautious of what is put in writing, whether it be in an e-mail, RACS ticket, note on a patient or prescriber file, or any other written form. There is no process in place to review these notes, but we will remove them when encountered." This email was sent in response to a note that stated "this may be a cash only pill mill??? verify and notate."

208. In an email dated October 2, 2015, regarding prescriber A.O., the same Government Affairs analyst stated “[w]e do not routinely monitor notes but we do have a responsibility to remove them if discovered during the review process.” The analyst went on to state that the only reason a ticket should be submitted is “to help identify trends in prescribing habits that may indicate a prescriber is making a significant contribution to the abuse and/or diversion of controlled substances that puts the DEA Registrations of our stores and McKesson’s warehouses at risk.” This email was sent in response to a ticket that complained that a prescriber was writing a high number of prescriptions for oxycodone and seeing out-of-state patients, both red flags recognized by Rite Aid.

209. On March 28, 2016, the same Government Affairs analyst directed a Third Party Industry Relations analyst to delete a note indicating that New York prescriber M.T. was “writing excessive dose[s] for oxycodone.”

210. In January 2016, that same Rite Aid Government Affairs analyst requested that Third Party Industry Relations monitor prescriber notes on a monthly basis. The Third Party Industry Relations employee thereafter ran a report every week to monitor notes added to prescriber files.

211. Likewise, on May 12, 2016, this same Government Affairs analyst directed the removal of notes from Prescriber V.O.’s profile. *See supra* ¶¶ 170-71. The notes included statements such as “DO NOT FILL CONTROLS,” “md under investigation,” and “Corporate monitoring this D.R. Possible suspicious activity.” The analyst’s email states that notes also were removed from the prescriber profile on October 20, 2015, and that Rite Aid had been monitoring this prescriber “since 2013” Despite this, notes were simply deleted, and district

managers were directed to tell their employees “to be mindful of everything that is put in writing”

212. By deleting these notes, Rite Aid’s Government Affairs Department attempted to hide that its stores were dispensing controlled substances based on invalid prescriptions. It also frustrated the ability of Rite Aid pharmacists to communicate effectively about suspicious prescribers with other Rite Aid pharmacists at other stores who might also be presented with prescriptions from those same prescribers.

7. Rite Aid Ignored Other Clear Warnings Present in Its Dispensing Data and Brought to Its Attention By Its Own Distributor

213. Rite Aid failed to heed the warnings present in its own dispensing data on prescriptions filled at its stores. That data, together with the pharmacist tickets and hard copy prescription records which only Rite Aid’s Government Affairs Department and its stores had access to, showed that Rite Aid knew it had filled unlawful prescriptions for opioids and other controlled substances.

214. For example, at least as early as September 2015, Rite Aid had data showing the top ten Rite Aid stores by total units dispensed of oxycodone 30 milligrams in each state where it operated. Rite Aid pharmacists at many of these same stores had previously submitted tickets about suspicious prescribing.

215. Store 01956 had the second highest total units of oxycodone 30 milligrams dispensed in Pennsylvania. Before September 2015, pharmacists at that store submitted at least five tickets to Rite Aid warning about suspicious prescribers and prescriptions, including for oxycodone.

216. By May 2016, a Rite Aid Regulatory Affairs analyst discussed with the Store’s District Manager “concerns identified in [Store] 1956’s prescription filling practices,” after

reviews showed that it was filling the highest percentage of a prescriber's amphetamine prescriptions, despite the fact that other Rite Aid pharmacies were located much closer to the prescriber's office. The Rite Aid Regulatory Affairs analyst considered these to be "[r]ed flags" and stressed that those "should be playing a part in" the Store's decision to fill. And yet, Rite Aid did not block the prescriber, alert its pharmacists to these prescribing practices, or apply additional scrutiny to prescriptions written by this prescriber. Rather, Rite Aid continued to fill the prescriptions.

217. Rite Aid's analysts knew from internal data which prescribers wrote the highest volume of prescriptions of frequently abused drugs, like oxycodone 30 milligrams, that were filled by Rite Aid Stores. Despite the fact that many of the top prescribers were already known to Rite Aid, as Rite Aid pharmacists had submitted tickets about many of the prescribers who appeared prominently in this data, Rite Aid nevertheless kept filling their prescriptions.

218. For example, as early as September 2015, Rite Aid's internal data on oxycodone 30 milligram dispensing showed that a Pennsylvania Rite Aid, Store 03637, had the fourth highest total units dispensed in the entire state. Furthermore, Store 03637 pharmacists also had submitted numerous tickets to Rite Aid about suspicious prescribers and prescriptions.

219. Rite Aid's controlled substance distributor, McKesson, which has separate responsibilities under the CSA to monitor suspicious orders from its clients, spotted these concerning trends and raised them with Rite Aid. In a November 2016 meeting, McKesson identified at least fourteen "outlier" stores for controlled substances and concerning drug purchase trends, one of which was Store 03637. After raising its concerns with Rite Aid, McKesson noted internally in its files that it would continue daily monitoring of those stores as Rite Aid's response was "reactive" rather than "proactive."

220. In a follow up meeting in December 2016 about those same stores and trends, McKesson again noted that Store 03637 in Pennsylvania was the “top purchaser of oxycodone and it has the highest ratio of oxycodone to total [prescriptions] when compared to all other Rite Aid stores.” Rite Aid explained that the store had “experienced serious challenges with thresholds” and that Store 03637’s pharmacy operated 24 hours a day.

221. McKesson reached out yet again in 2017 about this very same store and its dispensing of oxycodone. Discussing these questions internally, Rite Aid employees in Regulatory Affairs wrote internally in 2017 that Store 03637’s oxycodone dispensing was indeed trending upwards and that, compared to other stores in the same zip code, it “far outpace[d] all other stores in terms of oxycodone script count, percentage of oxycodone scripts to total and oxycodone unit volume.” Notwithstanding its acknowledgement of these troubling metrics, Rite Aid simply advised a supervisor overseeing the store to remind the pharmacists to follow the High Alert Review Process.

222. Rite Aid Regulatory Affairs Department ignored all of these warnings as well as its internal data, and Rite Aid Stores continued filling unlawful prescriptions.

223. In December 2017, Janet Hart acknowledged to Rite Aid senior management that Rite Aid could leverage existing tools “to identify outlier prescribers but at present there is not enough time to dive into the data.”

224. As alleged above, Rite Aid knowingly filled unlawful prescriptions for controlled substances at its stores. Rite Aid Corporation and its subsidiaries knew that these prescriptions were unlawful because Rite Aid employees in its Government Affairs Department knew that Rite Aid pharmacists filled prescriptions with clear red flags that indicated they were unlawful and prescriptions issued by suspicious prescribers, many of whom Rite Aid pharmacists complained

about to Government Affairs and whose prescribing history Government Affairs reviewed, often multiple times. Moreover, Rite Aid ignored clear indications of unlawful prescribing in Government Affairs' reviews of dispensing data and interactions with its distributor, and, by doing so, withheld important information from the pharmacists who dispensed prescriptions on its behalf. Nonetheless, Rite Aid Stores kept knowingly filling unlawful prescriptions for controlled substances.

225. As a result of the foregoing, Rite Aid knowingly caused false and fraudulent claims to Federal Healthcare Programs for controlled substances that had been dispensed without a valid prescription, were not for a medically accepted indication, and were not medically necessary. Rite Aid knowingly caused false certifications to Medicare, Medicaid, and TRICARE that were material to the payment of claims.

C. DEFENDANTS' FRAUDULENT CONDUCT WAS MATERIAL TO
FEDERAL HEALTHCARE PROGRAMS' PAYMENT DECISIONS

226. Compliance with federal and state requirements was, and still is, material to the United States' decision to reimburse claims for controlled substances. Compliance with such requirements is central to the Federal Healthcare Programs' benefits and is a condition of these medications being covered by these Federal Healthcare Programs.

227. Prior to at least 2014 and up through the present, Federal Healthcare Programs have publicly set forth the importance of these requirements as it relates to the prescribing of and payment for controlled substances, and opioids in particular.

228. For instance, CMS notified Part D Plan Sponsors in 2011 that they should take immediate steps to stop prescription drug misuse and fraud, noting the cost to Medicare for opioids like OxyContin and instructing Sponsors to investigate suspect claims and withhold payment for fraudulent claims. *The Obama Administration and Expanded Efforts to Fight*

Fraud, CMS (Dec. 13, 2011), <https://www.cms.gov/newsroom/fact-sheets/obama-administration-and-expanded-efforts-fight-fraud>.

229. Similarly, CMS issued public guidance to pharmacy providers in 2015 that discussed: Medicaid prescription drug expenditures; prescribing practices that could trigger audits; proper billing practices by pharmacy providers; and fraud, waste, and abuse. CMS further stated that “[a]buse may include improper payment for services, payment for services that fail to meet professionally recognized standards of care, or payment for services that are medically unnecessary,” with further reference to the FCA as an important tool for combating fraud, waste, and abuse. CMS, *Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care—Booklet 4: Billing Practices*, (2015), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf>.

230. In addressing opioid misuse in 2017, CMS again encouraged Part D Plan Sponsors to take action to investigate, audit, or terminate from their network prescribers who prescribe drugs improperly and pharmacies that dispense them. *Opioid Misuse Strategy 2016*, CMS (2017), <https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/cms-opioid-misuse-strategy-2016.pdf>.

231. Moreover, the HHS Secretary’s declaration that the opioid epidemic is a national public health emergency under federal law reflects the government’s concern that improper prescriptions continue to be prescribed and dispensed and the importance that the federal government places on curtailing such improper prescriptions.

232. When such prescriptions for controlled substances are not valid, are not issued for a legitimate medical purpose in the usual course of professional practice, or are intended for

purposes of addiction or recreational abuse, claims for such prescriptions are not eligible for payment by Federal Healthcare Programs.

233. For example, the U.S. Department of Justice has litigated or settled numerous actions where it was alleged that medical providers and/or pharmacies submitted claims for controlled substance medications to Federal Healthcare Programs that lacked a valid prescription, were not for a legitimate medical purpose and lacked a medically accepted indication, or that did not comply with State law. *See, e.g., Reckitt Benckiser*, <https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case> (\$700 million civil settlement with Reckitt Benckiser Group plc to resolve allegations that it violated the FCA by promoting the sale and use of addiction treatment drug Suboxone to physicians who were writing prescriptions that were unsafe, medically unnecessary and lacked a legitimate medical purpose); *United States ex rel. Rauch, et al. v. Oaktree Medical Centre, P.C., et al.*, No. 6:15-cv-01589-DCC (D.S.C.), <https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-south-carolina-chiropractor-pain> (complaint alleging that health care provider defendants violated the FCA by causing the submission of false claims to Federal Healthcare Programs for excessive and medically unnecessary opioid prescriptions); *United States ex rel. Norris v. Florence*, Civ. Action No. 2:13-cv-00035 (M.D. Tenn.), <https://www.justice.gov/usao-mdtn/pr/manchester-physician-barred-prescribing-certain-controlled-substances> (settlement with prescriber in which he agreed to be barred from prescribing schedule II and the vast majority of schedule III controlled substances); *United States ex rel. Denk v. PharMerica Corp.*, No. 09-cv-720 (E.D. Wis.), <https://www.justice.gov/opa/pr/long-term-care-pharmacy-pay-315-million-settle-lawsuit-alleging-violations->

controlled#:~:text=PharMerica%20Corporation%20has%20agreed%20to,to%20Medicare%20for%20these%20improperly (settlement with long-term care pharmacy alleging violations of the CSA and FCA for filling and billing Medicare for unlawfully filled prescriptions); *United States v. Spivack Inc. et al.*, No. 2:22-cv-00343 (E.D. Pa.), <https://www.justice.gov/usao-edpa/pr/philadelphia-pharmacy-and-owner-who-pled-guilty-agree-resolve-civil-fraud-and> (settlement of lawsuit brought under the CSA and FCA against pharmacy and its owner for unlawfully dispensing controlled substances).

234. It was reasonably foreseeable that Rite Aid's foregoing conduct of dispensing controlled substances pursuant to unlawful prescriptions would cause false and fraudulent PDE records, claims, and certifications to be submitted to and paid by the Federal Healthcare Programs.

Count I
False Claims Act: Submission of False Claims: 31 U.S.C. § 3729(a)(1)(A)
(All Defendants)

235. The United States repeats and realleges Paragraphs 1 through 234 as if fully set forth herein.

236. Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A). Specifically, Defendants knowingly presented, or caused to be presented, materially false or fraudulent claims for reimbursement for the dispensation of prescription drugs that were not for a medically accepted indication, lacked medical necessity, and/or were not authorized by valid prescriptions and consequently not eligible for reimbursement.

237. The Federal Healthcare Programs paid Defendants' claims for these false or fraudulent claims.

238. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation.

Count II
False Claims Act: False Records or Statements: 31 U.S.C. § 3729(a)(1)(B)
(All Defendants)

239. The United States repeats and realleges Paragraphs 1 through 234 as if fully set forth herein.

240. Defendants knowingly made, used, or caused to be made or used false records or statements in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B)—in the form of, inter alia, false claims data, false certifications, and false attestations—that were material to the payment of false or fraudulent claims for reimbursement by Federal Healthcare Programs for the dispensation of prescription drugs that were not for a medically accepted indication, lacked medical necessity, and/or were not authorized by valid prescriptions.

241. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation.

Count III
Unlawful Dispensing of Controlled Substances
21 U.S.C. §§ 829, 842(a)(1), 842(c)(1)(A), and 21 C.F.R. § 1306.04
Civil Penalties
(All Defendants)

242. The United States repeats and realleges Paragraphs 1 through 234 as if fully set forth herein.

243. Defendants knowingly dispensed controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of

professional practice in violation of 21 U.S.C. §§ 829(a), (b), and (c), and 842(a)(1); and 21 C.F.R. § 1306.04.

244. As a result of the foregoing, Defendants are liable to the United States for a civil penalty for each violation in an amount to be proven at trial, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

Count IV
Payment by Mistake of Fact
(All Defendants)

245. The United States repeats and realleges Paragraphs 1 through 234 as if fully set forth herein.

246. The United States seeks relief against Defendants to recover monies paid under mistake of fact. Federal Healthcare Programs paid Defendants for claims in connection with the dispensation of prescription drugs based on the mistaken and erroneous belief that the dispensations complied with federal rules and regulations governing the dispensing of prescriptions. This mistaken and erroneous belief, as well as the false representations and records made by Defendants concerning the claims, were material to the determination to pay for the claims.

247. If the Federal Healthcare Programs had known that the claims were controlled substance prescriptions that were dispensed pursuant to prescriptions that were not for medically accepted indications, lacked medical necessity, and/or were not authorized by valid prescriptions, they would not have paid the claims, resulting in damages to the United States in an amount to be determined at trial.

Count V
Unjust Enrichment
(All Defendants)

248. The United States repeats and realleges Paragraphs 1 through 234 as if fully set forth herein.

249. The United States paid Defendants for the dispensing of prescriptions that Defendants should not have received. Defendants retained and used these monies from the United States to which Defendants were not entitled and therefore were unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Defendants should not retain those payments from the United States, the amount of which is to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that judgment be entered in its favor and against Defendants jointly and severally as follows:

A. On the First Count, enter judgment in favor of the United States in the amount of its damages, trebled, plus penalties as allowed by law;

B. On the Second Count, enter judgment in favor of the United States in the amount of its damages, trebled, plus penalties as allowed by law;

C. On the Third Count, enter judgment in favor of the United States and impose a civil penalty for each and every violation of 21 U.S.C. §§ 829 and 842(a)(1) as allowed by law;

D. On the Fourth Count, enter judgment in favor of the United States in the amount of its damages plus prejudgment interest; and

E. On the Fifth Count, enter judgment in favor of the United States in the amount of its damages plus prejudgment interest.

Respectfully submitted,

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